ANIKA

Anika. *Restore Active Living.*™

OVOMotion®
with Inlay Glenoid

Total Shoulder Arthroplasty System

Value analysis committee | Product information kit

ANIKA

Anika is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. We partner with clinicians to understand what they need most to treat their patients and we develop minimally invasive products that restore active living for people around the world.

We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies.

Anika. *Restore Active Living.*™

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Product Benefits

Return to Form

Designed to maintain the native joint line and restore motion without restrictions, the OVOMotion® with Inlay Glenoid TSA System is reshaping the standard of primary TSA.[1,2]

- Designed to preserve native anatomy[2]
- High resistance to glenoid loosening[3]
- Designed to address Type A, B, and C glenoid classifications[1,2]
- Maximized efficiency in the ASC setting[4]
- Clinically proven excellence[5]

Designed to Preserve Native Anatomy

The nonspherical shape of the OVOMotion implant accurately replicates the shape of the humeral head, allowing for optimal range of motion and glenohumeral joint function.[2]

- Strong fixation with a threaded taper post*[6,7]
  - The threaded taper post and peripheral rim-fit anchor design demonstrated greater fixation strength at low bone mineral density when compared with other stemless designs[8]
- Reduces risk of overstuffing by maintaining glenohumeral stability and native soft tissue tension[7]
  - Maintains the height, volume and version of the joint with the combined nonspherical humeral head and inlay glenoid[6,7]

"...a more anatomical substitution on both sides of the joint may provide less stress on the subscapularis repair, rotator cuff, and other soft tissues, which may lead toward better motion and more accurate replication of the normal shoulder."[7]

Anthony Miniaci, MD

Deputy Chief Medical Executive, Baptist Health Orthopedic Care, South Florida

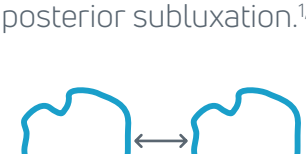
*See IFU for requirements regarding the use of bone cement.

Product Benefits

High Resistance to Glenoid Loosening with an Inlay Glenoid

The clinically-proven Inlay Glenoid enables a stable and reliable solution regardless of glenoid staging and posterior subluxation.[1,2]

10x greater resistance to loosening compared to an onlay glenoid[3]

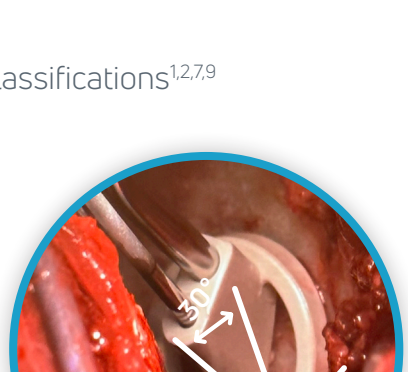


Mitigates the rocking horse effect[3]

Superior biomechanical stability compared to an onlay glenoid[3]

- Up to 43% less bone removed compared to onlay glenoid implants[6]
- Preserves peripheral glenoid base[3]
- Provides easy access to the glenoid with patented 30-degree angle reamer[2,4]
- Aims to maintain the native joint line[1,2]
- Designed to address Type A, B and C glenoid classifications[1,2,7,9]

True Inlay Glenoid



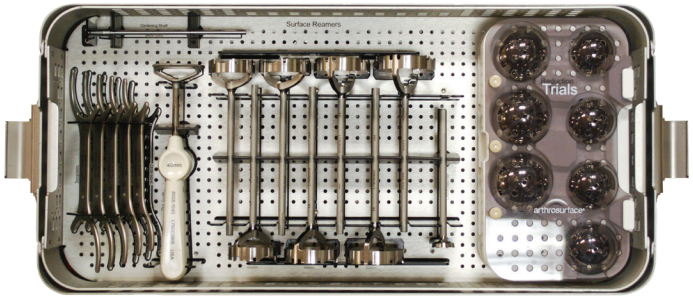
30-degree angle for easy glenoid access

Simplified, Efficient Procedure

With a simple technique and a single instrument tray,the OVOMotion with Inlay Glenoid TSA System is optimized for the outpatient environment.[1,4]

Streamlined Instrumentation[4]

- Single instrument tray with simplified design that follows the procedural flow[4]
- Glenoid instrumentation is completely disposable and optimized for efficiency[4]
- Fewer surgical steps compared to stemmed humeral implants[10]
- Optimal visualization of the inferior and posterior glenoid border using the humeral head reamer[4]
- ASC-friendly system[1,4]



Single, Streamlined Instrument Tray

Inlay Glenoid Disposable Instrumentation

Reduced Procedural Time

Clinical studies have shown that a stemless design has a significantly faster operative time compared to a stemmed TSA, which may reduce the risk of postoperative complications and unplanned reoperations.[2,11]

Clinically Proven

Clinically Proven Excellence

- 12+ years of clinical success[12]
- >8,300 implants used since launch[13]
- 9 clinical studies[5]
- Proven clinical outcomes at 68 months[9]

The OVOMotion with Inlay Glenoid TSA System Conserves and Preserves

Reduced Blood Loss[2]

79% **less blood loss** than traditional stemless designs[2]

83% **less blood loss** than stemmed design[2]

Minimal Bone Removal[6]

23% **less bone removed** than traditional pegged glenoids[6]

43% **less bone removed** than alternative caged glenoids[6]

Continuous Positive Outcomes

Significant improvement in range of motion[7,9,10,14,15,16,17]

Excellent patient satisfaction, with 94.3% of patients meeting or exceeding expectations[2]

High return to functional activities with minimal or no restrictions[1,2,7,15]

Anatomic glenohumeral re-centering across glenoid stages[10]

Reimbursement

Coding guide

Note: It is the Provider's responsibility to determine and submit appropriate codes for services that are rendered. This information is meant as a reference and should not be interpreted as providing clinical advice, dictating reimbursement policy, or substituting for the judgment of a practitioner.

Reimbursement laws, regulations, and payor policies change frequently, therefore, it is recommended that providers consult with their payors, coding specialists, and/or legal counsel regarding coverage, coding and payment issues.

Potential procedure codes include:

In-patient Setting

CPT Code	Description- Arthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement; example, total shoulder

MS-DRG	Description
483	Major Joint & limb reattachment procedure of upper extremity

Ambulatory Surgical Center/Outpatient Setting

CPT Code	Description	APC
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	5115

HCPCS Code

HCPCS Code	Description
C1776	Joint Device (implantable)

Surgical Technique

The OVOMotion System technique helps facilitate accurate and reproducible placement of the instrumentation and implants.

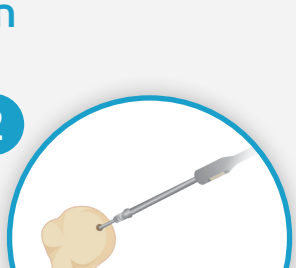
High level steps are outlined below. Please refer for the Technique Guide for detailed information. Please reach out to your local sales representative for an in-service training.

Humeral Preparation

1

Determine the size of humeral head and place Guide Pin in the humeral cortex

2

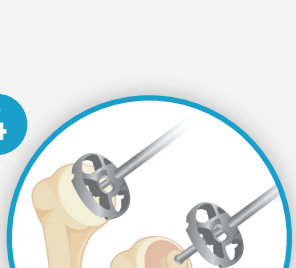


Advance the Centering Shaft

3

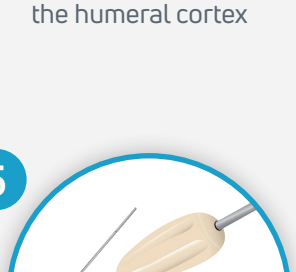
Ream with Surface Reamer

4



Ream with the Access Reamer

5

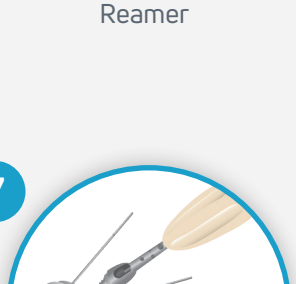


Assemble Preparation Trial and insert Pilot Drill

6

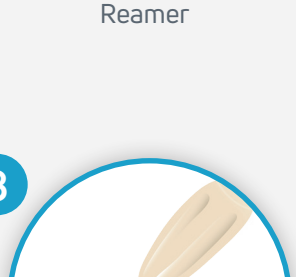
Insert Tap

7



Insert Taper Post and verify depth

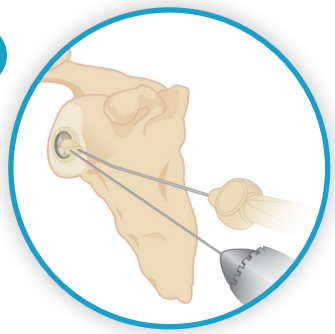
8



Secure Humeral Articular Component on Taper Post

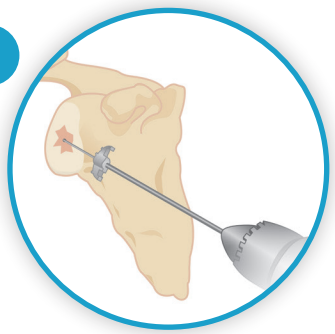
Glenoid Preparation

1



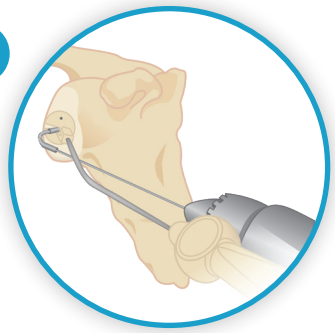
Place Drill Guide in inferior aspect of glenoid and secure with Guide Pin

2



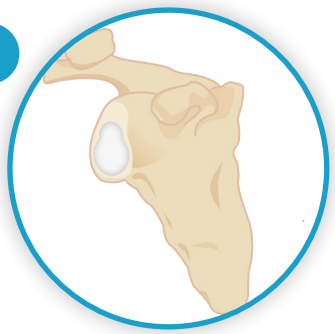
Ream with Inferior Glenoid Reamer

3



Use Glenoid Trial to verify trial is flush. Once confirmed, use Flexible Peg Drill to create tunnel for the Glenoid Peg.

4



Trial glenoid and cement into prepared glenoid surface. Secure glenoid with the Inlay Glenoid Impactor. Remove any excess cement.

Competitive Cross-Reference Chart

Company	Product	Humeral Head Shape	Humeral Head Material
Anika	**OVOMotion® Shoulder Arthroplasty System**	**Ovoid**	**Cobalt Chrome with Titanium Plasma Spray Coating**
Zimmer Biomet	Sidus® Stem-Free Shoulder	Spherical	Cobalt Chrome
Zimmer Biomet	Comprehensive® Nano Stemless Shoulder	Spherical	Cobalt Chrome
Stryker	Simpliciti™ Shoulder System	Spherical	Cobalt Chrome
Exactech	Equinoxe® Stemless Shoulder System	Spherical	Cobalt Chrome
Arthrex	Eclipse™ Total Shoulder Arthroplasty System	Spherical	Cobalt Chrome
Enovis (DJO)	Altivate® Anatomic CS Edge®	Spherical	Cobalt Chrome
Catalyst OrthoScience	Archer™ CSR Total Shoulder System	Ellipse and Spherical	Cobalt Chrome with porous coating
DePuy Synthes	INHANCE™ Shoulder System	Spherical	Cobalt Chrome

*UHMWPE: Ultra-high Molecular Weight Polyproplyene

	Humeral Fixation Method	Glenoid Material	Glenoid Type	Instrument Trays required for TSA	Disposable Glenoid Instruments?
	Center Fixation: Threaded Taper Post Peripheral Fixation: Yes	**UHMWPE**	**Inlay**	**1**	**Yes**
	Center Fixation: Press-fit; four open-fin anchors with porous coating Peripheral Fixation: None	UHMWPE	Onlay	2	No
	Center Fixation: Press-fit; six wings with porous coating Peripheral Fixation: None	UHMWPE	Onlay	2	No
	Center Fixation: Press-fit; tri-fin with porous coating Peripheral Fixation: None	UHMWPE	Onlay	3	No
	Center Fixation: Press-fit; porous bone cage with fins Peripheral Fixation: None	UHMWPE	Onlay	2	No
	Center Fixaxtion: Cage Screw and trunnion with porous coating Peripheral Fixation: None	UHMWPE	Onlay	2	No
	Center Fixation: Press fit; three serrated fins with porous coating Peripheral Fixation: None	UHMWPE with Vitamin E	Onlay	3	No
	Center Fixation: Press-fit posts with chamfeur cuts Peripheral Fixation: Yes	UHMWPE	Onlay	1	No
	Center Fixation: four open-fin anchors with porous coating Peripheral Fixation: None	UHMWPE with Vitamin E	Onlay	2	No

Instructions For Use

DESCRIPTION

The OVOMotion Shoulder Arthroplasty System includes:

1. Humeral articular component and a taper post fixation component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface;
2. Glenoid component intended to articulate with the humeral component when both articular surfaces of the shoulder joint are affected. The enclosed humeral articular component may be used with an appropriate Arthrosurface glenoid component (sold separately).

MATERIALS

Articular Component:	Cobalt-Chromium Alloy (Co-Cr-Mo), Surface Coating: Titanium (CP Ti)
Taper Post:	Titanium Alloy (Ti-6Al-4V)
Glenoid Component:	Ultra-High-Molecular Weight Polyethylene (UHMWPE)

INDICATIONS FOR USE

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty. Both humeral and glenoid components of the OVOMotion™ Shoulder Arthroplasty System are intended for cemented use only.

Patient Population

Patient Selection Factors to be Considered Include:

- Need to obtain pain relief and improve function.
- Patient age as a potential for early-age-revision of total joint arthroplasty.
- Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.
- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.

CONTRAINDICATIONS

Absolute contraindications include:

1. Defects that are located on joint surfaces that are discontinuous.
2. Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis.
3. Patients that have a known sensitivity to Cobalt-Chrome alloys typically used in prosthetic devices.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions.
2. Metabolic disorders which may impair the formation or healing of bone.
3. Infections at remote sites which may spread to the implant site.
4. Rapid joint destruction or bone resorption visible on roentgenogram.
5. Chronic instability or deficient soft tissues and other support structures.
6. Vascular or muscular insufficiency.

WARNINGS

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

Please refer to the electronic IFU for the most recent and full version. https://www.anikaifu.com/
IFU: PN 3001-2023 REV B

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned. When placing implant, carefully trim articular cartilage debris or osteophytes around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to postoperative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

These implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Their safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS
These implants are intended to be fitted and installed with the corresponding instrument set. Use of instruments from other systems may result in improper implant selection, fitting and placement, which could result in implant failure or poor clinical outcome. Instruments should be regularly inspected for any signs of wear or damage. Surgeon or Physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between the implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surface.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.
13. Embolism.

STERILITY
Implants and single-use disposable instruments are provided STERILE. Metallic implant components are sterilized by exposure to gamma radiation. Non-metallic implant components (sold separately) are sterilized by gas plasma sterilization. The single-use disposable instruments are sterilized by exposure to gamma radiation. Do not resterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date. Do not reuse implants or single-use disposable instruments. Reuse of these devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device(s).

CAUTION
United States Federal Law restricts this device to sale by or on the order of a physician.

FDA Clearance

April 18, 2018

Arthrosurface, Inc.
Dawn Wilson
VP, Quality & Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K173964
Trade/Device Name: OVOMotion™ Shoulder Arthroplasty System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder Joint Humeral (Hemi-Shoulder) Metallic Uncemented Prosthesis
Regulatory Class: Class II
Product Code: HSD, KWS
Dated: January 17, 2018
Received: January 18, 2018

Dear Dawn Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medical Education

Anika Medical Education's mission is to connect health care providers through meaningful education by providing them with the knowledge, skills and tools to restore active living in their patients.

Tailored programs to support practice advancement

Anika medical education programs are designed to provide clinicians with focused and flexible modalities, in-depth education on products and techniques, and interactive exchanges with other thought leaders.

Examples program includes:

- National courses and labs, lead by renowned faculty, on various orthopedic concepts.
- Visiting Surgeon Programs (VSPs) that provide surgical observation within an experts operating room.
- Surgeon to Surgeon (S2S) discussions on techniques, clinical evidence and products.
- Didactic and hands on experiences with thought leaders on current topics.
- Localized sawbones or cadaveric instruction labs designed to fit your schedule and patient needs.

Contact your Regional Director, Sales Manager or Local Anika Representative to learn about upcoming events or schedule a one-on-one demonstration.

Services and Support

Our commitment

Customer Service

Anika values our customers and is committed to providing quality support services. Whether it's placing orders, answering billing questions, providing cross references or sharing other documentation, our dedicated Customer Service Specialists are available and ready to assist you.

Anika Customer Service: 1-508-520-3003

Medical Services and Support

Our Medical Services and Support center was created to assist our customers in today's evolving healthcare environment. This unique support team provides technical and clinical information on procedures involving Anika products and/or other inquiries. Our support staff consists of knowledgeable health professionals, including surgeons, prepared to answer your questions and address your resource needs.

Anika Medical Services and Support: 1-508-520-3003

Reimbursement Hotline

Anika has partnered with reimbursement experts at MCRA to provide a dedicated hotline for reimbursement and coding questions. MCRA's coding, reimbursement, and compliance experts have over 50 years of combined healthcare policy and finance services experience, and have a proven track record servicing over 250 clients nationwide. The Anika dedicated hotline is available via phone or email and inquiries should expect a response within 24hrs. All coding inquiries are answered by a credentialed, coding specialist.

Contact Information:

MCRA Phone: 800-436-1377

MCRA Email: USReimbursement@anika.com

Packaging and Sterilization

OVOMotion TSA System Implants
OVOMotion TSA System implants are individually packaged and are sterile. The shelf-life is seven years.

OVOMotion TSA System Instrument Tray
There is one OVOMotion TSA instrument tray. The instrument tray is provided non-sterile.

To clean and sterilize the instrument tray, please follow the detailed instructions in the instrumentation tray Instructions for Use.

High-level information is outlined below:

Cleaning: Clean instruments by hand in warm water with an appropriate neutral pH detergent. Do not use steel instruments. Rinse instruments after cleaning with distilled water and dry.

Sterilization: Steam sterilization on the Vacuum cycle, at 270° F/132° C. The minimum exposure time is 4 minutes. The recommended dry time is 30 minutes. The instrument trays should be processed in double wrapped configuration using an FDA-cleared sterilization wrap. Sterilizing in liquid solutions is not recommended and do not sterilize at temperatures greater than 275° F/135° C.

Glenoid Implants
The Inlay Glenoid implants are individually packaged and are sterile. The shelf-life is seven years.

Glenoid Instruments
The Inlay Glenoid instruments are provided in an individually packaged instrument kit. They are sterile, single-use instruments. The shelf-life is 5 years.

Packaging

Upper Tray

Lower Tray

Ordering Information

OVOMotion Total Shoulder Arthroplasty System

Instrument Systems	
8000-5000	OVO Instrumentation Kit
8000-5300	OVOMotion Instrumentation Kit

Taper Post (Fixation)	
8156-0032-W	Taper Post, 12.0mm x 32mm
8H00-0100	Pin Kit, Shoulder, OVO

OVOMotion® Humeral Articular Components	
8HM2-4642-W	Humeral Component, 46mm x 42mm, OVOMotion
8HM2-4844-W	Humeral Component, 48mm x 44mm, OVOMotion
8HM2-5046-W	Humeral Component, 50mm x 46mm, OVOMotion
8HM2-5248-W	Humeral Component, 52mm x 48mm, OVOMotion
8HM2-5450-W	Humeral Component, 54mm x 50mm, OVOMotion
8HM2-5652-W	Humeral Component, 56mm x 52mm, OVOMotion
8HM2-5854-W	Humeral Component, 58mm x 54mm, OVOMotion

Inlay Glenoid System

Instrument Systems	
G000-0100	Inferior Glenoid Instrument Kit (Sterile, Disposable)
G000-0200	Superior Glenoid Instrument Kit (Sterile, Disposable)
G000-0300	Disposable Reamer 15mm, Glenoid
G007-1410	2.0mm Guide Pin, Glenoid

Inlay Glenoid Components

Inferior Glenoid Component - Single	
G203-2010-W	Articular, 19 x 20mm, Implant, Glenoid, 58/55 Head, 1mm offset
G203-2015-W	Articular, 19 x 20mm, Implant, Glenoid, 53/50 Head, 1.5mm offset
Superior Glenoid Component - Double	
G203-2515-W	Articular, 20 x 25mm, Implant, Glenoid, 58/55 Head, 1mm offset
G203-2520-W	Articular, 20 X 25mm Implant, Glenoid, 53/50 Head, 1.5mm offset

Notes

References

1. Yalcin, S., Scarcella, M., Everhart, J., Samuel, L., & Miniaci, A. (2021). Clinical and radiographic outcomes of total shoulder arthroplasty with a nonspherical humeral head and inlay glenoid in elite weight lifters: A prospective case series. *Orthopaedic Journal of Sports Medicine*, 9(7), 232596712110210.
2. Uribe JW, Zvijac JE, Porter DA, Saxena A, Vargas LA. Inlay total shoulder arthroplasty for primary glenohumeral arthritis. *J Shoulder Elbow Surg International*. 2021 5(6):1014-1020.
3. Gagliano JR, Helms SM, Colbath GP, Przestrzelski BT, Hawkins RJ, DesJardins JD. A comparison of olay versus inlay glenoid component loosening in total shoulder arthroplasty. *J Shoulder Elbow Surg*. 2017 Jul;26(7):1113-1120.
4. Data on file.
5. Publications available upon request.
6. Preclinical data on file.
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