AMERICAN ASSOCIATION OF SURGEON DISTRIBUTORS
Setting standards, protecting patients.

ETHICAL PHYSICIAN OWNED DISTRIBUTORSHIP

Thank you for your interest in becoming a member of the American Association of Surgeon Distributors (AASD). The AASD was formed for the purpose of developing and maintaining standards governing the legal and ethical operation of surgeon-owned medical device distributorships.

Surgeon-owned distribution is an emerging model with great potential benefits to society, hospitals, patients, and surgeons. Like any model, however, there is the potential for abuse and so there is a need to put effective safeguards in place.

The Standards established by the association will serve to protect patients, hospitals, and society. Patients will be assured of rigorous product evaluations, proper disclosures, and a higher degree of personal accountability for the product. Hospitals that insist on membership in the Association for any distributorship with surgeon ownership will be assured that the distributorship will operate in compliance with the most recent laws governing such relationships, and be assured the distributorship will provide qualified and well trained product representatives, thoroughly evaluated and FDA-cleared products, and pricing that represents the lowest cost for like implants. Society will be assured that the distributorship will function primarily to provide healthcare savings on outstanding products.

In order to be granted membership, the distributorship must demonstrate that it satisfies the Standards set forth by the Association. This will require that the distributorship provide:

1. Utilization data
2. Investment and ownership percentage for all owners
3. Proof of written contracts with hospitals and vendors (pricing from vendors is not required)
4. Attestation from hospitals that the distributorship is the lowest average cost vendor of like implants and that referrals were not leveraged
5. Proof of patient and hospital disclosure
6. Attestation of Compliance form signed by each owner
7. Proof of adherence to all AASD Policies if audited

Distributorships seeking membership must attest that they follow all of the standards and policies established by the AASD (attached).

Please mail, email, or fax the completed application to the address or number listed below.

www.AASDonline.org • P.O. Box 8631, Redlands, CA 92375
(e) kpugar@aasdonline.org • (p) 909-748-5759 • (f) 888-663-2349

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Standards and Policies

Surgeon-Owned Distributorship: A company that distributes medical devices and collects payment from hospitals, surgery centers or other third party payers, and has ownership comprised of referring surgeons who collectively own more than 10% of the company.

Standards and Criteria for Membership:

1. Distributorship maintains a business structure consistent with Federal Self-Referral and Anti-Kickback statutes, and reports in compliance with the Physician Payment Sunshine Act.
2. Distributorship demonstrates merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.
3. Distributorship annual price increases to customers do not exceed 3% above the consumer price index (CPI).
4. Distributorship is a legitimate, free-standing stocking Distribution Company with employees, contracts, an address, a business license, and insurance.
5. Distributorship demonstrates adherence to the AASD Product Evaluation Policy.*
6. Distributorship demonstrates adherence to the AASD Employee Training Policy.*
7. Distributorship demonstrates adherence to the AASD Disclosure Policy.*
8. Distributorship demonstrates adherence to the AASD Investment and Distribution Policy.*
9. Distributorship submits utilization data annually and demonstrates adherence to the AASD Appropriate Use Monitoring Policy.*
10. Distributorship has written contracts with hospitals, with pricing that is consistent among hospitals, and contract periods of at least one year.
11. Distributorship does not leverage referrals to any hospital or surgery center.
12. Distributorship does not require, pressure, or otherwise leverage physician owners' use of the Distributorship devices.

**Expanded definitions below*

Product Evaluation Policy:

The product evaluation policy ensures that surgeon owned distributors have a formal program in place to review and qualify Vendors, and to review and analyze the quality and value of implants prior to supplying those implants to customers. Where applicable, this process includes ensuring adherence to a contracted hospital's value analysis program prior to introduction and use of products.

Vendor Qualification

The distributorship shall review and qualify each Vendor prior to purchasing any products from that Vendor. Vendor qualification shall specifically include, but not be limited to, the following:

1. Evidence of valid, current product liability and completed operations insurance with minimum limits of $1,000,000 per occurrence, $2,000,000 aggregate
2. Evidence of valid FDA entity registration and FDA compliant quality systems
3. Review of FDA database information including product recalls, notices, warning letters, or any other relevant product or company information
4. Vendor is not on the debarred listing

Product Selection and Assessment

All products shall be subject to the following procedures prior to being approved for purchase and sale. Product acceptance shall require:

1. Product design features that are established by the surgeons
2. Evidence of FDA approval or 510k clearance by means of official documents
3. Comparison summary of comparable implants to include design attributes, functionality, performance, and mechanical testing if published
4. References of other surgeons currently using the products, if appropriate

Employee Training Policy:

It is crucial to the operations of a well-run surgeon owned distributorship that the product representative is well trained and has an educated understanding of surgical procedure, including sterile technique and corporate compliance. The product representative is an important asset to a compliant distributorship, and proper training is vital. The distributorship must provide written evidence of the Representative's:

1. Training in sterile technique
2. Training in the sterilization procedures required for each set
3. Product competency from each product vendor
4. Company compliance training
5. HIPAA compliance training
6. AdvaMed Code of Ethics and Compliance training
7. Acknowledgement and acceptance of Distributorship policies and procedures
8. Compliance with qualifications and reporting requirements of a contracted hospital's vendor credentialing program, where applicable

Disclosure Policy:

The AASD disclosure policy applies to Distributor physician owners and serves to maintain integrity and full transparency with patients and colleagues. Distributorship must ensure:

1. In-office patients receive a written disclosure
2. Ownership disclosure is displayed in a visible area within the office
3. All contracted hospitals are informed prior to the use of product that the Distributorship has surgeon ownership
4. Colleagues are informed that the Distributorship has surgeon ownership

Investment and Distribution Policy:

Distributorship corporate and operating documents must evidence the following:

1. Ownership is determined by each surgeon's investment interest
2. Ownership after start-up is set and does not vary with volume of potential referrals
3. Any profits are distributed proportionate to ownership interests
4. Distributorship does not require mandatory termination of a physician owner's interest for a physician's failure or inability to use Distributorship devices.

Appropriate Use Monitoring Policy:

To ensure that the operation of an AASD certified distributorship does not result in any inappropriate increases in the utilization of implanted medical devices, the American Association of Surgeon Distributors has established the Appropriate Use Monitoring Policy and Program.

Appropriate Use Monitoring Program

The decision for surgery is governed sufficiently by published guidelines, peer review, utilization review, and community medical standards. Thus, the physician's recommendation for surgery and implant choice is guided by these factors, not by any perceived inducement. AASD and its ePOD certified distributorships are committed to the premise that instrumentation should only be used by qualified surgeons when medically indicated. This program is designed to monitor the medical appropriateness of implant cases when a physician member's utilization practice profile for instrumentation increases disproportionately compared to other clinical practice indicators. It is critical to note that the data measured is generated by the physician's clinical practice and includes all procedures without regard to whether that procedure included an implant from AASD applicant distributorship or another implant company.

As part of the initial certification and annual renewal, each applicant distributorship shall submit practice profile data elements for each Physician Member. Required practice profile data elements are based on commonly accepted procedure codes (CPT) that will be aggregated into a baseline practice profile for that surgeon. Annually, the previous year's data elements shall be aggregated and compared with the baseline profile and prior year. A net change greater than 15% from the prior year that is not proportionate to non-implant related practice predictors (e.g. total patient visits) shall initiate a series of audits that will either, 1) validate the profile change and reset the surgeon's baseline, 2) initiate a medical chart audit by an independent auditor, or 3) result in Board action which may include probation, denial of the application, or the revocation of the distributorship's AASD certification.

Practice Profile Date Elements

- Years in Practice and Specialty
- Years at current primary office practice location
- Total patient visits in previous 12 months
- Total surgical procedure by type in previous 12 months

Independent Auditor

An independent auditor shall be required to perform all probationary and suspension reviews. An auditor must meet the following qualifications:

- For spine implant review: Board certified by the American Board of Neurosurgery, the American Board of Orthopedics with Spine Fellowship training, or the American Osteopathic Board of Orthopedic Surgery with Spine Fellowship training
- For non-spine implant review: Board certified by the American Board of Orthopedics or the American Osteopathic Board of Orthopedic Surgery
- Minimum of 7 years in surgical practice within the appropriate specialty
- In active practice and in good standing with appropriate medical licensing boards
- Must not perform surgical cases at any of the hospitals of the surgeon that is the subject of review

All audit cases shall be de-identified (patient and surgeon) prior to review. Please refer to the AASD website for the algorithm used for monitoring utilization patterns of physician members.

Confidentiality Policy:

Safeguarding confidential information is a fundamental obligation of the AASD. The Executive Director will assure and maintain the confidentiality of all information provided on behalf of a distributorship's application. All identifying information will be redacted prior to submission to the Board for review.

Note: If a distributorship does not meet certain criteria for membership, the Executive Director will request a resubmission of the application once the deficiencies have been reconciled.

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Membership Application

All information provided will be held confidential for use of granting membership to the association only. Member company names remain confidential unless otherwise authorized

Applicant Information

Distributorship Name:		Business License Number:
Address:		Year Distributorship Started:
City:	State:	Zip:
Phone:	Fax:	Email:
Lead Service Rep Name:		
Phone:	Fax:	Email:

Hospital Information

Hospital Name:		**Address:**
City:	State:	Zip:
Contact Name:	Title:	☐ authorized to contact
Phone:	Fax:	Email (required):
Hospital Name:		**Address:**
City:	State:	Zip:
Contact Name:	Title:	☐ authorized to contact
Phone:	Fax:	Email (required):
Hospital Name:		**Address:**
City:	State:	Zip:
Contact Name:	Title:	☐ authorized to contact
Phone:	Fax:	Email (required):

Fees

Membership fees are determined by number of owners. Starting at $1,850 for the 1st owner, with $300 each additional owner, not to exceed $4,550. Membership fee is due with application and is due annually.

Amount Due:$	Amount Payable by Check to: American Association of Surgeon Distributors

Attestation please initial the following *(failure to initial all will delay processing)*

_____ Our distributorship abides by Federal Self-Referral and Anti-Kickback statutes, and reports in compliance with the Physician Payment Sunshine Act.
_____ Our distributorship is the lowest cost provider of implants to our hospitals, and pricing is consistent among our hospitals.
_____ (If Reapplying) Our distributorship has kept annual price increases below 3% over the consumer price index (CPI).
_____ Our distributorship adheres to the AASD Product Evaluation Policy, Employee Training Policy, Disclosure Policy, Investment and Distribution Policy, and Appropriate Use Monitoring Policy.
_____ Our distributorship has not leveraged our referrals while contracting with hospitals, and does not pressure the use of our devices among our owners.
_____ Our distributorship is committed to strictly following all standards established by AASD and those outlined in our signed Attestation of Compliance.

Supporting Documents Checklist *(failure to submit application with supporting material will delay processing)*

If reapplying, verify that the information and attached documents are still accurate and current. Document any necessary changes.

- ☐ Complete the attached ownership information form
- ☐ Complete the attached utilization forms (as many as necessary)
- ☐ Complete the attached Attestation of Compliance form
- ☐ Attach your disclosure documentation
- ☐ Attach the front and back page of your signed contracts with vendors and hospitals
- ☐ Include check for membership fees

Authentication

Applicant authorizes that the information given is accurate. By signing, you are doing so on behalf of the entire company.

Upon acceptance as a member in the American Association of Surgeon Distributors, the applicant agrees to abide by the criteria for membership and will comply with any request for audit made by AASD.

Signature of authorized applicant:	Date:
Print:	OFFICE USE:

Ownership Information Form

Shareholder/Member Information			
(All names and information remain confidential for association use only)			
Name	Email or Phone	% Ownership	Amount Invested

Additional Hospitals

Hospital Name:		**Address:**	
City:		State:	Zip:
Contact Name:	Title:		☐ authorized to contact
Phone:	Fax:	Email (required):	

Hospital Name:		**Address:**	
City:		State:	Zip:
Contact Name:	Title:		☐ authorized to contact
Phone:	Fax:	Email (required):	

Hospital Name:		**Address:**	
City:		State:	Zip:
Contact Name:	Title:		☐ authorized to contact
Phone:	Fax:	Email (required):	

Utilization Data Collection
Total Joints

Surgeon Owner: _____

Data Source: _____
(may be asked to supply original data documents)

Date of Distributorship Formation:_____ Date of AASD Application:_____

Instructions:

- Fill out this sheet for each surgeon owner of the distributorship.
- Each cell of data must represent a 12-month period of time relative to distributorship formation (or date surgeon joined distributorship) and date of application.
- Complete surgical utilization for all devices, not just those carried by the distributorship.
- Bi-lateral joint procedures are to be listed as two procedures.

Data Collection Period	**12 months prior to formation of distributorship**	**First 12 months of distributorship**	**Prior 12 months (if applicable)**	**Current 12 months**
Dates (mm/yy-mm/yy)				
Patient Visits				
New patient visit (99241-99245 & 99201-99205)				
Procedures				
Primary Total Knee Replacement (27447)				
Primary Total Hip Replacement (27130)				

Please use the space below to provide any details about the changes in your practice that may have contributed to changes in your practice complexion.

_____
_____
_____
_____
_____
_____
_____

TO THE BEST OF MY KNOWLEDGE THE PRECEDING DATA IS ACCURATE:

X_____ _____
(Physician Signature) (Print Name) (Date)

X_____ _____
(Individual who supplied data Signature) (Print Name) (Date)

Utilization Data Collection
SPINE

Surgeon Owner: _____

Data Source: _____
(may be asked to supply original data documents)

Date of Distributorship Formation:_____ Date of AASD Application:_____

Instructions:

- Fill out this sheet for each surgeon owner of the distributorship.
- Each cell of data must represent a 12-month period of time relative to distributorship formation (or date surgeon joined distributorship) and date of application.
- Complete surgical utilization for all devices, not just those carried by the distributorship.
- Multi-level spine procedures are to be listed as a single procedure.

Data Collection Period	**12 months prior to formation of distributorship**	**First 12 months of distributorship**	**Prior 12 months (if applicable)**	**Current 12 months**
Dates (mm/yy-mm/yy)				
Patient Visits				
New patient visit (99241-99245 & 99201-99205)				
Procedures				
Posterior Thoracic, Lumbar, Sacral, and Iliac Instrumentation (22840-22844)				
Anterior Cervical Fusion (22551)				
Application of Lumbar structural interbody device (22851)				

Please use the space below to provide any details about the changes in your practice that may have contributed to changes in your practice complexion.

_____
_____
_____

TO THE BEST OF MY KNOWLEDGE THE PRECEDING DATA IS ACCURATE:

X_____ _____
(Physician Signature) (Print Name) (Date)

X_____ _____
(Individual who supplied data Signature) (Print Name) (Date)

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Attestation of Compliance

We, the members of _____, attest and confirm our commitment to develop and maintain a medical device distribution company that will consistently comply with all federal and state laws, while demonstrating a significant value to patients, society and local healthcare.

1. Ethical Conduct. To ensure patients' and society's best interests are served, we, the members of _____, will hold ourselves to high ethical and moral standards of conduct. We endorse that patients who entrust their medical care to a physician have the right to expect that those physicians will favor the patient's best interest over their own interests at all times.

2. Preservation of Choice. To safeguard patients, we, the physician members of _____, will support the physician member's responsibility to choose medical devices based on the best interest of the patient. To support physician member's choice, the physician members will not exert undue pressure or facilitate negative company action toward a physician member with regard to medical device choice or failure to use a medical device not supplied by _____.

3. Disclosure. To ensure transparency, we, the physician members of _____, will provide disclosure to our patients, hospitals and colleagues of our financial interest in _____, a company that will distribute medical devices to local hospitals and surgery centers.

4. Pricing. To ensure value and demonstrate merit, we, the physician members of _____, will utilize our clinical and product knowledge on behalf of local hospitals and surgery centers to purchase, stock, and distribute high quality products, and achieve cost savings for hospitals, surgery centers, and federal and commercial payors. To ensure full accountability, we encourage hospitals and other participating entities to seek an independent Fair Market Analysis of _____ pricing.

5. Referrals. To safeguard hospitals, we, the physician members of _____, will never raise the specter of undue influence or condition our referrals in any manner, on the hospitals use of devices distributed by _____.

6. Quality Assurance/Product Evaluations. To ensure quality, we, the member of _____, will only distribute products that meet or exceed the quality of products currently utilized by our physician members and others in the community. We will perform diligent product evaluations consistent with our Quality Management and Compliance Program and will only distribute products that have been cleared by the United States Food and Drug Administration.

7. Utilization. To ensure that the operation of _____ will not result in any inappropriate increases in the utilization of implanted medical devices, we the members of _____ will provide implant utilization data and related practice data from twelve (12) months preceding the development of the distributorship and annually thereafter. We agree to an independent outside audit of our utilization consistent with our Appropriate Use Monitoring Policy. We understand that information collected regarding utilization will be used solely for the forgoing purposes,

and will not be used for the purpose of encouraging any investors to maintain or increase their use of implants through _____.

8. Member Training. We, the members of _____ will participate in, and provide for training to all members regarding compliance with Federal and State Self Referral and Anti-kickback Statutes, HIPAA Compliance, AdvaMed Compliance, Quality Management Programs, Disclosure Policy, Product Evaluation Policy, and Appropriate Use Monitoring Policy.

9. Personnel Training. We, the members of _____ will provide initial and continuing comprehensive training to employees and contracted personnel regarding compliance with Federal and State Self Referral and Anti-kickback Statutes, HIPAA Compliance, AdvaMed Compliance, and Operational Policies and Procedures. We will also provide our product representatives with comprehensive training to ensure technical proficiency with products and related instrumentation consistent with our Personnel Training and Credential Requirements.

10. Investment/Risk/Active Involvement. We, the members of _____ have provided substantial personal investment into the formation of this distribution company and understand that such investment entails risk and does not represent a guarantee of return. We will remain at all times actively involved in the business of _____ which involves, but is not limited to, product evaluations, clinical evaluations of potential new products and technologies, purchase of approved products, managing product inventories, dispensing products, and providing training to our product representatives and potential members.

11. American Association of Surgeon Distributors (AASD). We, the members of _____, will apply and diligently maintain membership in the American Association of Surgeon Distributors. This Association is a public non-profit Association founded to establish, promote and guard legal and ethical standards governing surgeon-owned distribution companies. Membership in AASD represents our commitment to the highest ethical standards in all aspects of this operation and will convey to beneficiary hospitals, surgery centers, third party payors, and all concerned that _____ has demonstrated compliance with all Standards established by the Association.

Members:

I, _____, Member I, _____, Member

I, _____, Member I, _____, Member

I, _____, Member I, _____, Member

I, _____, Member I, _____, Member

I, _____, Member I, _____, Member

hereby attest that the foregoing commitments and compliance measures are accurate and will be adhered to by all members of _____, LLC.

Date: _____