



ZIMMER BIOMET
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COMPLIANCE MANUAL FOR SCREENED BUSINESS PARTNERS

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Our mission at Zimmer Biomet is to alleviate pain and improve the quality of life for people around the world. We commit to the highest standards of patient safety, quality, and integrity; our pledge to conduct business ethically is a vital part of our culture. In order to achieve our mission and uphold our legacy, we only do business with third parties who demonstrate our same level of commitment to ethical business practices. We absolutely prohibit giving bribes or anything of value for an improper purpose.

We depend on third parties, like you, to conduct business on our behalf all over the world, and we have a due diligence screening process in place to ensure our third parties have a history of operating in accordance with all applicable laws, regulations, and industry codes. All third parties who are required to complete Zimmer Biomet's due diligence process must adhere to the requirements and expectations of (i) Zimmer Biomet's Code of Business Conduct and Ethics and (ii) this Compliance Manual (except distributors and sales agents in the United States and Canada, which must follow the U.S. and Canada Sales Distributor and Direct Territory Compliance Manual).

Auditing and monitoring activities, along with periodic due diligence renewals and annual check-ins, are a key part of our Compliance program to ensure continued commitment to ethical business practices by our third parties.

Following this manual is part of your contractual obligations to Zimmer Biomet, and failure to do so will result in negative consequences, up to and including termination of our agreement with you.

Compliance Training

All employees of your organization who are involved in Zimmer Biomet business, including Finance, Sales and Marketing managers, logistics, and other administrative staff, must be trained on Zimmer Biomet's compliance requirements. You may contact your Zimmer Biomet Representative for training materials.

All employees involved in Zimmer Biomet business must also attend or complete all trainings offered or assigned by Zimmer Biomet Compliance. Please remember that it is your responsibility to keep attendance records of all trainings.

The training will help you to understand the Zimmer Biomet Compliance requirements by going through scenarios and case studies with simple explanations. It will also review lessons learned from audit and investigation findings and explain how rules are applied correctly to satisfy Zimmer Biomet's Compliance requirements. Wherever possible, trainings are conducted in local language.

The scope of the trainings will include Zimmer Biomet's Code of Business Conduct and Ethics, anti-corruption and anti-bribery requirements, and the contents of this manual.

Appointment of Sub-Distributors

In some countries it is common practice for distributors to appoint sub-distributors. This may help the business operate, but at the same time can also increase the risk for Zimmer Biomet. Zimmer Biomet and you are both responsible and liable for any misconduct of a sub-distributor. Sub-distributors are expected to follow the same ethical standards that are required of you for all Zimmer Biomet business. Therefore, it is important that you follow the steps below when you want to engage a sub-distributor:

- **Contract with sub-distributor:** You must enter into a contract with the sub-distributor to bind it to the same Zimmer Biomet compliance conditions that you have, including:
 - Zimmer Biomet's Code of Business Conduct and Ethics
 - This Manual
 - Applicable laws and regulations (such as the U.S.FCPA) and industry codes
 - Right to audit
- **Training:** It is your obligation to provide regular compliance training to the sub-distributor and to ensure that you maintain records of this training (e.g., email communication or attendance records). You should provide Compliance training to sub-distributors at least every year.
- **Auditing:** You are responsible for your sub-distributors and must ensure they uphold the terms of their contract and avoid misconduct. We perform auditing and monitoring activities and expect sub-distributors to provide access to relevant records when requested.

Sub-distributors are appointed by a Zimmer Biomet distributor to take ownership of, sell, and distribute Zimmer Biomet Products. Sub-distributors do not include: (1) group purchasing organizations (as determined by Zimmer Biomet Compliance); (2) entities purchasing fewer than three non-stocking orders per year from a Zimmer Biomet distributor; (3) distributors of other brands that purchase instrumentation from Zimmer Biomet for use when servicing a surgery and not to resell individually; and (4) entities that work on behalf of HCP entities to optimize their logistics operation processes.

- **Notification:** Inform your Zimmer Biomet Representative that you want to engage a sub-distributor. This needs to be done prior to any engagement of a sub-distributor.
- **Due Diligence:** The sub-distributor must undergo due diligence by Zimmer Biomet before any business can be conducted.
- **Approval:** Written approval from Zimmer Biomet must be obtained before any sub-distributor is used for Zimmer Biomet business.
- **Contract Amendment:** Your distribution contract with Zimmer Biomet may be amended to reflect the engagement of the sub-distributor.

Conflicts of Interest

You must avoid using family or other close relationships to improperly influence purchasing decisions by HCPs and Public Officials.

Conflicts of Interest (COIs) pose a compliance risk to Zimmer Biomet and your company. Therefore, it is critical to understand, and identify and mitigate potential COIs.

Understand: A **Conflict of Interest** can occur when an individual's personal interests (e.g., family, financial, or social factors) – could impact his or her judgment, decisions, or actions in the workplace.

Identify: The following are examples of potential conflicts of interest, which require disclosure and a compliance review to assess if there is a necessary mitigation:

- One of your owners, shareholders or employees is an HCP or Public Official
 - An **HCP** is any individual or entity, within the continuum of care of a patient, which may purchase, lease, recommend, use, prescribe, or arrange for the purchase or use of Zimmer Biomet products and services.
 - **Public Official** is any officer, agent, employee, or any person acting for or on behalf of:
 - A government, including any legislative, administrative, or judiciary branch
 - Any department, agency, or arm of a government, including wholly or majority state-owned or controlled businesses
 - Any public international organization, such as the United Nations or World Health Organization
 - A political party
 - Any candidate for political office
- You are selling products to an HCP who is one of, or a close family member of one of your owners, shareholders, or employees.
 - A 'close family member' includes parents, siblings, spouses or partners, and children, grandparents, grandchildren, step-relatives, in-laws, cousins, and other similar individuals.
- You are hiring an employee who has been recommended by an HCP

Mitigate: If you are aware of a potential or actual conflict of interest, reach out to your Zimmer Biomet Representative or to the Compliance team to assess the situation and determine any further action. Always remember: transparency allows Zimmer Biomet and its business partners to uphold the company's high ethical standards!

Books & Records Accuracy

Companies must maintain **Books and Records** that provide an accurate, true, and fair view of all transactions—including cash transactions—relating to Zimmer Biomet business. This includes, but is not limited to:

- Documentation related to the marketing and sale of Zimmer Biomet products
- Documentation related to discounts, rebates, and pricing concessions
- Documentation related to other high-risk processes discussed below, such as conference support materials and educational items, evaluation and demonstration products, and educational grants and charitable donations
- Cash and non-cash payments to and for an HCP or to any third party
- Anything of value provided to any HCP, customer, or third party

Records must be contemporaneous and sufficiently detailed to understand the nature and purpose of the expense or transaction.

Important: You should limit the use of cash in Zimmer Biomet related transactions.

From time to time Zimmer Biomet will conduct an audit of your business activities and books and records to ensure the maintenance of such books and records, including adequate documentation. It is therefore crucial that you segregate Zimmer Biomet transactions from other manufacturers in your accounting records, for example, by using a system to record Zimmer Biomet related expenses with a unique accounting code that is easily distinguishable from other manufacturer's expenses.

Discounts, Rebates and Pricing Concessions

When providing a discount, rebate, or pricing concession relating to Zimmer Biomet Products make sure you adhere to the following requirements:

- Verify that there is a legal, legitimate, commercially reasonable, and transparent reason for the discount, pricing concession, or rebate
- Retain written documentation of the specific terms and conditions of how the discount, rebate, or pricing concession will be earned and the justification for the discount
- Ensure that discounts, rebates, and pricing concessions comply with all applicable laws
- Record all discounts, rebates, and pricing concessions accurately in books and records and maintain records relating to approvals of all discounts
- All discounts should be reflected on the invoice and there should be no after-sales discounts (i.e., credit notes or adjustments to selling price documented as a discount)
- Selling price after discount should not be below total cost of goods.
- Terms and conditions should indicate whether exchanges are allowed.

Tender Submissions

You might participate in tenders on behalf of Zimmer Biomet. Tenders are generally led by or involve HCPs and Public Officials. When dealing with HCPs and Public Officials related to a tender, refer to the guidance on **Interactions with HCPs**. You must request Zimmer Biomet Compliance approval if the tender submission includes:

- Any expenses other than reasonable application fees and associated costs and travel expenses, or
- Any products, services, or funding, separate from the Zimmer Biomet Products that are the subject of the tender and that are offered free-of-charge or at a discount.

To request approval for a tender:

- Contact your Zimmer Biomet Representative and ask for the “Tender Pre-Approval Form”
- Submit the form to your Zimmer Biomet Representative at least 10 days prior to tender submission.
- The Zimmer Biomet Representative will provide you with the feedback/approval.

Marketing and Promotion

When you are doing marketing and promotional activities with regards to the Zimmer Biomet business, there are a couple of points that you must consider. Marketing activities cannot be used to improperly influence HCPs. They must have legitimate business purposes and cannot involve HCP entertainment or leisure travel. Also, make sure you follow these guidelines:

- The hosting location should:
 - Be modest, convenient, and not overly luxurious.
 - Be in close proximity to HCPs (e.g., no extensive travel required to reach the location)
 - Not feature entertainment, leisure, or recreational amenities
- Make promotional activities available to customers independent of their potential or actual volume.

Always remember: You cannot provide cash or other forms of compensation for HCPs to attend these promotional activities.

Social Media

We recognize that the responsible use of social media can benefit the public and our customers; however, to ensure that patient privacy is protected and to avoid misinformation about our products, health conditions, and treatment options, all social media activity related to Zimmer Biomet business for commercial use must be consistent with our policy on the use of Social Media.

Please contact your Zimmer Biomet Representative for a copy of the Social Media policy.

Interactions with HCP

Under appropriate circumstances, meals, travel, or accommodations related to a legitimate business purpose may be provided to HCPs and Public Officials. You must never provide meals, travel, or accommodations to HCPs or Public Officials to gain or retain business or business advantages.

Please see below the requirements you must follow:

Meals

To provide a meal to an HCP or Public Official, it must be:

- Permissible under local laws
- A clear business purpose in connection to providing scientific, educational, or business information
- Occasional only, modest in perception, and reasonable in price (refer to the Meal Limits for HCPs and Public Officials at Appendix A for Zimmer Biomet’s own hospitality limits)
- At an appropriate location for a business meeting
- Not include guests; only those directly involved in Zimmer Biomet business may attend.

Be aware that your representative should be present throughout the entire meal.

Important: Business meals need to be documented and accounted in the books and records for audit purposes! This documentation must include:

- All attendees: full name, position and hospital/employer
- Business purpose
- Name and address of restaurant
- Itemized receipt

Travel and Accommodation

In limited situations and only in close collaboration with Zimmer Biomet can you arrange and pay for HCPs travel and accommodation.

You may provide appropriate travel and accommodation to HCPs for:

- Participation in Zimmer Biomet Medical Education events
- Participation in Zimmer Biomet organized facility tours (e.g., ZBEdge Discovery Day)

When you book travel and accommodation, always make sure the following conditions are met:

- Travel must be limited to a direct itinerary to and from the HCP's primary place of residence and the location of the event
- The travel dates must be tailored to the event(s) dates
- Air travel for HCPs must generally be booked in economy or economy plus class
- Business class cannot be booked if no leg of the scheduled trip is more than five hours (local rules may require longer legs)
- Always request prior approval of the proposed travel arrangements by the Zimmer Biomet Events Management team or your Zimmer Biomet Representative

Important: You cannot provide travel and accommodation for participation in Third Party Educational Conferences (TPEC) directly to HCPs.

Booking Method: You must book travel and accommodation through:

- Zimmer Biomet directly (contact Zimmer Biomet Events Management team or your Zimmer Biomet Representative)
- Zimmer Biomet approved travel agency
- Directly through an airline's website, hotel's website, or an online booking provider

Recordkeeping: Travel and accommodation expenses need to be documented and accounted in the books and records for audit purposes! This documentation should include at least:

- Itinerary documenting the HCPs travel

details (incl. dates, schedule, class, fare)

- Invoice for flights, train and accommodation
- Receipts for all ground transportation and incidental charges (e.g., baggage fee)

Restrictions: You may not:

- Provide, arrange, reimburse travel and accommodation for anyone who does not have a business purpose to attend the event (for instance, the spouse or guest of an HCP).
- Incur any extra expenses or make arrangements to extend or modify travel arrangements for personal reasons
- Provide, arrange or reimburse any entertainment for an HCP
- Provide an HCP with any per diems, pocket money, or other cash and cash equivalents
- Provide first class flight tickets

No Entertainment & Gifts

Entertainment and gifts are not permissible. This applies to HCPs, Public Officials and/or their close family members.

Cultural Courtesies

In certain countries in Latin America and only as permitted under applicable local laws and industry codes, **Cultural Courtesies**, which are small, low-value, and / or perishable items, may be provided. Contact your Zimmer Biomet Representative for additional guidance.

Giving cash or cash equivalents, such as gift certificates, vouchers, or coupons, even as a cultural courtesy, is strictly prohibited.

Conference Support Materials and Educational Items

Only in limited situations may conference support materials and educational items be permissible. Contact your Zimmer Biomet Representative before providing any items.

Conference support materials are used during conferences, are of low value, and are Zimmer Biomet branded. Unless local law prohibits, you can provide conference support materials to HCPs. Examples of these are:

- Pens
- Paper notebooks
- Tote bags

Educational items benefit patients or serve an educational purpose for the HCP. They do not have an independent value to the HCP outside of their professional responsibilities. Unless local law prohibits, you can provide educational items to HCPs. Examples of these are:

- Textbooks
- Anatomical models

Important: Contact your Zimmer Biomet Representative for pre-approval when you plan to provide conference support materials or educational items.

Evaluation and Demonstration Products

Evaluation and Demonstration products are free of charge to the customer and can only be provided on a need basis, in limited quantities and infrequently. They must never be given to improperly influence the purchase, lease, recommendation, use or prescription of Zimmer Biomet products.

Evaluation and Demonstration products are at your cost and Zimmer Biomet will not reimburse.

Evaluation products are consumable or durable products used during a real surgery. They can be provided to HCPs to allow the HCP to assess the appropriate use and functionality of the product. The mandatory criteria for providing an evaluation product are:

- HCP must be new to the specific technique or Zimmer Biomet product, or has not evaluated the technique or Zimmer Biomet product in the last 12 months, or there is a legitimate need to evaluate it again.

- Patient cannot be charged for the evaluation product
- Written disclosure to Zimmer Biomet of use of evaluation and no-charge products
- They cannot be provided as a form of compensation for an HCP

The use of capital equipment for evaluation purposes requires prior approval by Zimmer Biomet Compliance.

Demonstration products can be provided for HCP and patient education under certain conditions. Demonstration products must be permanently marked or engraved with language clearly indicating that the product is for demonstration purposes only and not for implantation and human use. If the product is too small to be engraved or marked, the packaging can include such wording as well.

All requests to provide HCPs with Zimmer Biomet products as an Evaluation or Demonstration Product must be documented and retained. Documentation should include:

- Recipients name/hospital
- Date of providing evaluation product
- Date of providing/return date for demonstration products

HCPs may not resell, charge, or seek reimbursement from government or commercial payors for any free-of-charge Zimmer Biomet products or services, and you should disclose this in writing to HCP recipients of Evaluation and Demonstration products.

Educational Grants and Charitable Donations

When providing educational grants and charitable donations in connection to Zimmer Biomet business, you must adhere to the following restrictions:

Educational Grants: You cannot independently provide such grants. You may only provide educational grants through the Zimmer Biomet grants review process. The following educational grants may be provided:

- Third-party medical education (incl. grants for Third Party Educational Conferences)
- Research activities/initiatives
- Educational conferences, and
- Patient and public educational initiatives

Important: Even if an educational grant has been approved by Zimmer Biomet, you cannot select a specific HCP to attend a TPEC, whether as a delegate or a speaker. Therefore, you cannot directly pay or reimburse the expenses of any individual HCP. You can only support the attendance of an HCP by providing a TPEC Grant to an organization or hospital.

Please contact your Zimmer Biomet Representative for additional guidance and submit your requests to the Zimmer Biomet Grants Office.

Charitable Donations: You can independently provide such donations if there is no connection to potential Zimmer Biomet product use or referral.

Educational grants and charitable donations need to be documented and accounted in the books and records for audit purposes!

Engagement of HCPs

You may not engage HCPs as consultants for medical education or any other services related to Zimmer Biomet business. The only exception is where Zimmer Biomet is not already providing training in your country. Contact your Zimmer Biomet Representative if you see the need for an HCP engagement, prior to any engagement.

Trade Compliance

As the headquarters of Zimmer Biomet is in the US, you are required to comply with US and other applicable export administration regulations, embargo, sanction, and anti-boycott programs for any Zimmer Biomet related activities.

Distributors and agents are required to make sure that Zimmer Biomet products are not diverted, re-exported or otherwise provided to any destination or party that is not allowed by the distribution agreement or would violate any export control or sanction programs such as:

- [OFAC sanctions program](#)
- Listed on the "[List of Parties of Concern](#)"
- [U.S. Anti-boycott Laws](#)
- [EU Sanctions Regulations](#)
- [Swiss Export Control Policy and Sanctions/Embargos](#)

You are required to verify that all necessary documentation is obtained prior to the importation or delivery of Zimmer Biomet products.

Important: Zimmer Biomet does not permit the hand carry of any Zimmer Biomet product across borders due to restrictions and declaration requirements of Customs authorities worldwide. Hand carrying refers to carrying on one's person or within one's luggage while traveling.

Transparency Reporting

In certain countries medical device manufacturers must report payments made to HCPs and Public Officials. It is your responsibility to fulfill this requirement if applicable in your country. Therefore, you must ensure that you keep records of all payments and transfers of value that result from your interactions with HCPs and Public Officials. Examples of such payments and transfers of value are:

- Meals
- Travel and accommodation expenses
- Educational items and grants
- Consulting payments

Please contact your Zimmer Biomet Representative for additional guidance.

Compliance Audit

We expect the highest standard of integrity and ethical business practices from our business partners. This also means that we will from time to time check if our business partners comply with our requirements. Audits will evaluate business partners on any and all requirements that are described in Zimmer Biomet's Code of Business Conduct and Ethics and this Manual.

The scope for such an audit may include:

- a review of the sales and marketing expenses related to Zimmer Biomet business, such as:
 - educational grants,
 - exhibit booth and marketing expenses,
 - charitable donations,
 - gifts and entertainment,
 - travel accommodations,
 - business courtesies,
 - advertising and promotional expenses, and
 - HCP consulting payments,
- bank transactions,
- petty cash and cash advances,
- prepayments and loans,
- accounts receivable,
- pricing and discounts, and
- inventory management.

An audit can be divided into three stages:

- **Planning:** You will be contacted by your Zimmer Biomet Representative to inform you of an audit and to find a time for the audit fieldwork that works for you and Zimmer Biomet. Several weeks before the fieldwork, you will receive a document request list and a questionnaire to help the audit team scope their work. As a next step, the audit team will select samples which you will be requested to provide supporting documentation. At this stage the audit team will also check if translation support for documents and interviews is needed.
- **Fieldwork:** The fieldwork may take one to two weeks. During this time, you will be requested to be available for interviews and follow-up questions to samples and processes. You will receive regular updates from the audit team and at the end, the audit team will present you the preliminary observations.
- **Reporting:** The audit team will finalize the audit report after Zimmer Biomet's internal review of the audit results and remediation action plans.

You can find below some lessons learned and common observations identified, that you can easily prevent when being audited:

- Ensure that all employees who work on Zimmer Biomet-related business receive compliance training and that training records are kept on file
- Make sure you only engage sub-distributors in accordance with Zimmer Biomet requirements, in particular: pre-approval, contracting and training
- Maintain proper documentation when providing discounts and rebates
- Maintain documentation when providing meals to HCPs
- Disclosure of changes in ownership

Scope of Services

You may only provide services within the scope of your contract and/or distribution agreement with Zimmer Biomet.

SPEAK UP HOTLINE



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Compliance Hotline

At Zimmer Biomet, we are committed to creating a culture in which business partners and team members at every level feel comfortable raising their hand when they see something wrong. Whenever you have a concern about a potential or actual violation of Zimmer Biomet policies, procedures, or internal controls you have many options for speaking up without the risk of retaliation.

Our Code of Conduct and Ethics strictly prohibits retaliation against anyone who raises concerns. If you see something, you should say something – to your Zimmer Biomet Representative or to Compliance.

Please note that you must also immediately notify us if you are contacted by a government investigator in relation to Zimmer Biomet business. You must also notify us of any known or suspected violations of any law, regulation, industry code, government health care program requirement, Zimmer Biomet's Code of Business Conduct and Ethics, or the requirements in this Manual, even if not directly related to Zimmer Biomet products.

Reports should be made directly to Zimmer Biomet Compliance or the Zimmer Biomet Speak Up Hotline.

- Visit: zimmerbiomet.com/speakup
- Call: Country-specific phone numbers are located on the website
- Email: compliance.hotline@zimmerbiomet.com

Below are five important things to know about the Compliance Hotline:

- It's a confidential reporting tool to raise concerns about potential or actual violations of Zimmer Biomet policies, procedures and internal controls

- It's designed for anonymous reporting where possible per local legislation
- It's operated by an independent company, not Zimmer Biomet
- It's part of our compliance program
- It's supported by our Zimmer Biomet leadership team

Reports to the Speak Up Hotline are followed up by the Zimmer Biomet Global Compliance Investigations team. In cases where we substantiate allegations, Zimmer Biomet will determine next steps. Depending on the severity of the misconduct, the results can include termination of the business relationship.

Appendix A

ZIMMER BIOMET MEAL LIMITS FOR HCPS AND PUBLIC OFFICIALS

Region	Location of the Meal	Meal Limits (per person, including tax and gratuity)			
		Currency	Breakfast	Lunch	Dinner
	Canada	CAD	50	75	150
	Mexico	MXN	520	1,500	1,500
	United States of America	USD	50	75	150
	Other Americas Countries	USD	35	50	125
APAC	Australia	AUD	45	75	150
	China (PR)	CNY	220	400	600
	Hong Kong (SAR)	HKD	270	500	1,000
	India	INR	2,000	2,500	5,300
	Indonesia	IDR	175,000	350,000	850,000
	Japan	JPY	4,400	5,500	11,000
	Korea	KRW	44,000	88,000	110,000
	Malaysia	MYR	120	140	270
	New Zealand	NZD	45	75	150
	Philippines	PHP	550	950	2,700
	Singapore	SGD	45	90	140
	Taiwan	TWD	1,100	2,000	3,500
	Thailand	THB	1,100	1,300	3,500
	Vietnam	VND	750,000	860,000	2,350,000
	Other APAC Countries	USD	35	50	100
EMEA	Belgium*	EUR	25	40	80
	Czech Republic	CZK	800	1,350	2,150
	Denmark	DKK	230	400	800
	Euro Zone	EUR	30	50	80
	Finland	EUR	30	50	110
	France*	EUR	30	50	50/70*
	Greece*	EUR	30	50	70
	Hungary	HUF	10,430	18,285	28,600
	Iceland	ISK	4,000	6,500	17,000
	Norway	NOK	300	500	1,300
	Poland	PLN	135	240	380
	Portugal	EUR	30	50	60
	Romania	RON	145	245	405
	Saudi Arabia	SAR	135	230	370
	South Africa	ZAR	525	925	1,445
	Sweden	SEK	300	500	1,100
	Switzerland	CHF	36	60	125
	UAE	AED	135	225	430
	UK	GBP	28	47	75
	Other EMEA Countries	USD	35	50	100

*Additional meal limit restrictions apply. Please ask your Zimmer Biomet representative for more information.