Mobi-C® Cervical Disc Prosthesis
Enhanced Surveillance Study

Surgeon Annual Survey

REPORTING SURGEON AND CLINICAL CENTER INFORMATION	
Reporting surgeon name	
Reporting Surgeon Contact information	Phone: Address: Email:
Clinical center/institute	
Name of person at facility to contact	
Contact information	Phone: Address: Email:
1) Have you implanted patients with any Mobi-C devices during the past year?	☐ Yes ☐ No
2) Approximately how many patients have you implanted with Mobi-C within the past year?	Approximate number of patients: _____
3) In the past year, have you observed any of the following in <u>ANY</u> of your past Mobi-C patients: ****If you have observed any of the events or conditions listed above, Attachment 1 will need to be completed per event (one per patient experiencing one of these events or conditions).***	☐ Heterotopic Ossification ☐ Device Malfunction ☐ Device Removal ☐ Other Serious Device-Related Complication

Please complete Attachment 1 for each patient experiencing any events or conditions listed in Question 3.

Please complete and return to:
Email: **ESSsurvey@zimmerbiomet.com** Phone: 512-344-3317 Fax: 303-484-6855
Mail: 13785 Research Boulevard, Suite 200, Austin, TX 78750, USA

ATTACHMENT 1	
PATIENT INFORMATION	
Patient ID #	
Patient Sex	☐ Male ☐ Female
Patient Age at Date of Visit	
Patient Race/Ethnicity	
Patient Diagnosis Pre-Implantation	
Did the event result in any of the following to the patient?	☐ Death ☐ Life-threatening ☐ Required inpatient hospitalization or prolonged hospitalization ☐ Required medical or surgical intervention to prevent permanent impairment/damage of a body function or permanent damage to a body structure ☐ Disability or permanent damage ☐ Other medically important events (in the opinion of the surgeon) ☐ None of the above
Condition of patient following event?	
PRODUCT INFORMATION	
Article Number (Product Part #)	
Product Lot #	
Device Size	
Level(s) Where Device(s) Implanted	
Level(s) Where Event Occurred	
If removed, was product returned (or will product be returned)?	☐ Yes ☐ No ☐ Unknown
EVENT INFORMATION	
Date of Original Surgery - Date device was implanted (mm/dd/yy)	
Date of Event (mm/dd/yy)	

Event Type (check all that apply)	☐ Device break ☐ Device loosening ☐ Implant migration / subsidence ☐ Implant malpositioning ☐ Heterotopic ossification (see section below) ☐ Infection ☐ Instability/pseudoarthrosis (non-fusion) ☐ Nerve injury/dural tear ☐ Pedicle/vertebral fracture ☐ Vascular Injury ☐ Wound Hematoma ☐ Other, specify_____
Please provide a detailed description of the event	
Was the event related to the device?	☐ Definitely device-related: there is a definitive causal and/or temporal connection between the event and the device. ☐ Possibly device-related: there is a reasonable possibility that the adverse event may have been primarily caused by the device ☐ Probably not device-related: there is no reasonable possibility that the adverse event may have been caused by the device ☐ Unrelated: there is no causal connection between the event and the device.
Did the event result in any of the following to the patient?	☐ Death ☐ Life-threatening (immediate risk of death) ☐ Required inpatient hospitalization or prolonged hospitalization ☐ Resulted in persistent or significant disability or incapacity ☐ Necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure ☐ was a congenital anomaly or birth defect ☐ None of the above

Action Taken	☐ None ☐ Medication Required ☐ Intra-op ☐ Post-op ☐ Surgical Intervention: (Date: _____) If yes, was device removed? ☐ Removed ☐ Not Removed ☐ Intra-op ☐ Post-op (*complete **Intervention** Section below)* ☐ Other (specify):_____
Which X-rays/images will be sent to LDR spine? (check all that apply)	☐ AP ☐ LAT ☐ F/E ☐ CT ☐ MRI ☐ Fluoro ☐ Other (specify): _____ ☐ None, Please explain:_____
What is the timeframe of the images being sent? (check all that apply)	☐ Original surgery ☐ Pre-op ☐ Intra-op ☐ Post-op _____Wks
Specify the narrative/notes from the surgeon that will be sent to LDR Spine (e.g. op notes, radiology)	
INTERVENTION INFORMATION	
Date of Intervention (mm/dd/yy)	
Please indicate the type of surgery performed	☐ **Removal** – all of the original system configuration is removed with or without replacement ☐ **Revision** –adjustment, modification or removal of part of the implant configuration, with or without replacement of a component (may also include adjusting the position of the original configuration) ☐ **Supplemental Fixation** – additional instrumentation is implanted (e.g. supplemental placement of a rod/screw or a plate/screw system) ☐ **Reoperation** – any surgical procedure at the involved level(s) that does not involve removal, modification, or addition of any components to the system ☐ **Other** – surgical procedures not described above (please describe below):

HETEROTOPIC OSSIFICATION INFORMATION	
If checked box above, describe, e.g., location, degree, measurements taken using the table below as a guide:	

Assessment	Definition
0 - Class 0	No evidence of osteophyte formation or heterotopic ossification.
1 - Class I	HO is detectable in the front or sides or the vertebral body, or as islands of bone in the adjacent soft tissue, but is not in the intervertebral disc space. Bone is not present between the planes formed by the two vertebral endplates.
2 - Class II	HO is growing into the disc space. Bone is present between the planes formed by the two adjacent endplates but is not significantly blocking or articulating between adjacent vertebral endplates or osteophytes.
3 - Class III	The range of motion of the vertebral endplates is blocked by the formation of HO and/or postoperative osteophytes on flexion-extension radiographs, but some movement of the prosthesis still remains.
4 - Class IV (Bridging Bone)	HO is causing bony ankylosis. An apparent continuous connection of bridging bone exists between the adjacent vertebral endplates with little or no motion occurring across the treated segment.
5 - Indeterminate	A reliable determination cannot be made from the available imaging due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view due to parallax effects or other imaging artifacts. The cause will be documented.
6 - Unable to Assess	The relevant images are missing or unavailable for review, or the relevant anatomy is not visible in the field of view.

Please provide any additional information relevant to the event and/or device	