Site Initiation Visit Report

REFERENCES	
Study ID: **H-34 DELTA REVISION**	
Study Title: **An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup.**	
Principal Investigator: **Dr. Jerzy Białecki**	
Study site:	**Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP** **Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland**
Study site ID: **01**	
Date of visit: **11 June 2021**	

ATTENDEES	
Sponsor personnel (including roles)	Study site personnel (including functions)
Adam Kogut (CRA)	Dr Jerzy Białecki (PI)
	Dr Paweł Bartosz (SI)
	Dr Julia Macias (SI)

* In case of NO, comment is mandatory

Item	Yes	No*	NA	Comments
1.Study protocol				
1.1 Has Confidentiality Agreement signed?	☒	☐	☐	
1.2 Has Clinical Trial Agreement fully signed?	☒	☐	☐	
1.3 Has Investigator Brochure/Instruction for Use reviewed and discussed?	☒	☐	☐	IFU was discussed with the site staff including the indication of use of the study device.
1.4 Has study protocol been discussed and reviewed?	☒	☐	☐	The study protocol Version 1.1 dated 28 September 2020 was discussed with the study team including the inclusion/exclusion criteria, subject's visits and study procedures.
1.5 Have ICH-GCP and ISO 14155 requirements been reviewed?	☒	☐	☐	Both ICH-GCP and ISO-14155 requirements and PI's obligations were discussed and reviewed during the visit.
1.6 Have ICH-GCP certificate for site staff collected and/or training performed?	☒	☐	☐	The ICH-GCP requirements were discussed with the site staff. The ICH-GCP training was documented on the Site Training Log.
2. Informed consent and enrolment procedures				
2.1 Has process of obtaining and documenting Informed Consent been reviewed and discussed?	☒	☐	☐	The process for obtaining the informed consent was discussed with the site staff along with ICF sections that should be completed personally by the investigator and the patient. The site will follow ICH GCP and ISO 14155 rules during the patients' consenting. ICFs will be personally signed and dated by each subject prior to any study related procedure and by the investigator conducting the discussion and obtaining the consent. The site will provide each participant with a copy of the signed and dated consent form. The consenting process will be documented in subjects' medical documentation.
2.2 Have advertisement procedures been explained?	☒	☐	☐	The advertisements will not be used in this study as all advertisements have to be first approved by the EC.
2.3 Have routine practice of subject referral and treatment discussed?	☒	☐	☐	
2.4 Has subject number assignment and randomisation procedures reviewed?	☒	☐	☐	Subject number assignment process was explained to the site staff. Randomization is not applicable (study is not randomized).

* In case of NO, comment is mandatory

Item	Yes	No*	NA	Comments
2.5 Have study enrolment period, study duration, commitments and timeline discussed?	☒	☐	☐	
3. Regulatory & IEC/IRB				
3.1 Have IEC/IRB approval (date of approval) obtained?	☒	☐	☐	The study was approved by EC on 09 September 2020 (initial approval). The study protocol v. 1.1. was submitted to EC on 24 November 2020 for information only.
3.2 Has Regulatory authority notification/ approval (date of approval) obtained?	☐	☐	☒	Regulatory approval is not applicable for this study.
4. Source Documents				
4.1 Original source documents identified? *Specify if paper or electronic medical charts.* *Establish who enters data in the e-CRFs, Diary Cards, questionnaires, etc.* *In case of e-source data and monitor has not confidential directly access, check if printout dated and signed can be filed in patient's notes*	☒	☐	☐	The site uses electronic source documentation, however, all medical history will be printed out and placed in the subjects' binders. CRA can have access to the electronic version od the source documentation to be able to compare the printed out documentation with the electronic data. All investigators will be responsible for eCRF completion.
4.2 Was availability and monitor's direct access to all subject source documents during monitoring visits discussed?	☒	☐	☐	
5. Investigator site file and archiving				
5.1 Investigator site file received and reviewed?	☒	☐	☐	ISF and Patient Questionnaires were provided to the site.
5.2 Is ISF completed and accurate? *Please attached completed Investigator Site FIle checklist*	☒	☐	☐	The site staff were informed regarding the ISF maintenance, archiving and safekeeping of all files and documents. More specifically the site staff were instructed to keep all study-related correspondence, submissions and approvals in the appropriate sections of the ISF handled over during the visit. Furthermore, they were instructed to safely store the ISF and all study related documents in a secure and locked cupboard, and access to it will only be granted to the delegated members of the site.
5.3 Has archiving and document retention requirements discussed?	☒	☐	☐	The documentation will be archived on site's facility. Archiving: 15 years as per the local regulation.

* In case of NO, comment is mandatory

Item	Yes	No*	NA	Comments
6. Case report form (CRF)/eCRF				
6.1 Have CRF/eCRF reviewed and CRF/eCRF training completed and documented?	☒	☐	☐	The eCRF training was performed and documented for all study staff. During the visit the Demo eCRF version was used to train the study staff.
6.2 Have the CRF / eCRF and list responsible staff for data entry, queries answer, signature discussed?	☒	☐	☐	All investigators will be responsible for eCRF completion and answering queries.
6.3 Has security / passwords policy / procedure discussed?	☒	☐	☐	
7. Site staff qualifications				
7.1 Has CV (signed and dated) of the principal investigator been archived in ISF and collected?	☒	☐	☐	PI's CV dated 08 June 2020 is present in the ISF.
7.2 Have CVs (signed and dated) of Sub-Investigators been archived in ISF and collected?	☐	☐	☐	CV of Dr Macias dated 11 June 2021 and CV of Dr Bartosz dated 11 June 2021 are present in the ISF.
7.3 Have CV (signed and dated) of other site staff been archived in ISF and collected?	☐	☐	☒	The study staff is composed from PI and 2 Sub-Investigators only.
7.4 Have tasks and responsibilities of the investigator and the study team been explained and reported correctly in the delegation log? *Please see attached a copy of delegation log*.	☒	☐	☐	The study team is composed from Dr Jerzy Białecki (PI), Dr Paweł Bartosz (SI) and Dr Julia Macias (SI). PI and both SIs will be responsible for performing all study procedures, subjects' recruitment, consenting, SD and e-CRF completion.
8. Safety Reporting				
8.1 Have AEs/SAEs reporting procedures and timelines been explained?	☒	☐	☐	The site staff has been informed to carefully report and record in the Limes eCRF all AE/SAE incidents that have been experienced by their patients during or after surgery with DELTA Revision acetabular cup. SAEs that come to their knowledge after the signing of the ICF, should be reported in the Limes eCRF within 24h.
8.2 Have ADEs/SADEs/DDs reporting procedures and timelines been explained?	☒	☐	☐	It was discussed that SAE, SADE, USADE and device deficiency that could have led to an SADE should be reported to the Sponsor within 24 hours of learning about them.
9. Monitoring procedures				
9.1 Have the monitoring procedures and frequency been discussed?	☒	☐	☐	The site staff was informed that the approved monitoring plan will be followed throughout the duration of the study. Monitoring

* In case of NO, comment is mandatory

Item	Yes	No*	NA	Comments
				visits will occur every 2-4 months during the enrolment period and every 3-6 months during follow-up period until Last Patient Last Visit (LPLV).
9.2 Was the Investigator and study personnel involvement at monitoring visits discussed?	☒	☐	☐	
10. Investigational device storage & accountability				
10.1 Has instructions for handling of Investigational device and trial related materials reviewed?	☐	☐	☒	The study device will be supplied within commercial way.
10.2 Has device storage requirement and storage security reviewed?	☐	☐	☒	Study is post-market, therefore there is no need to check for device storage.
10.3 Has device shipment, dispensing, accountability, destruction & return procedures reviewed?	☐	☐	☒	Study is post-market, therefore there is no need to check for device shipment, dispensing, accountability, destruction & return procedures
11. Central Radiology				
11.1 Will a central Radiology be used for this study? If yes, has central radiology requirements discussed?	☒	☐	☐	The anonymized X-rays data will be uploaded directly in the eCRF
11.2 Has investigator's responsibilities regarding the central radiology discussed?	☒	☐	☐	
12. Local Laboratory				
12.1 Will a local laboratory be used for this study?	☐	☐	☒	Routine laboratory evaluations will be performed locally in accordance with current local practice but will not be collected in the eCRF.
12.2 Has the Laboratory accreditation/certification and normal ranges been obtained?	☐	☐	☒	
13. Miscellaneous				
13.1 Any other significant comments should be clearly documented	☒	☐	☐	The site staff was informed that the medical history and all other relevant medical documents confirming subject' eligibility and study related activities must be present at the site. The study questionnaires should be completed by the site staff based on subject's answers. The following documents were collected during the visit: - CV of Dr Macias and Dr Bartosz - Study Site Duty Delegation Log - Study Contact List

* In case of NO, comment is mandatory

Item	Yes	No*	NA	Comments
				- Site Visit Log - Delegation of Consent for Processing of Personal Data for Dr Białecki, Dr Macias and Dr Bartosz - Source Data Location List - Site Training Log

List of open issues after the visit:

ISSUES/RISKS**					
Issue number	Identified date	Description/action required	Interim/Final resolution	Resolved by	Resolved date
1	11Jun2021	Answer the following site staff questions: 1. As per protocol the Subject ID should be 01-01 (for fist subject), however, the EDC assigns no. 1/1 for first subject. The question is, should the site use 01-01 or 1/1 as Subject ID in the study logs? 2. Should the site report in the eCRF pain as an AE as this occurs almost in all cases after the surgery? 3. Should the joint dislocation be reported as SAE?	1. Use the numeration as detailed in the protocol (01-01)	01Jul2021	

****To be reported in the next monitoring visit report (report issue number)**

	Role	Name and Surname	Date	Signature
Written by:	CRA	ADAM KOGUT	14/7/2021 | 10:13 CEST	DocuSigned by: Adam Kogut Signer Name: Adam Kogut Signing Reason: I am the author o Signing Time: 14/7/2021 | 10:12 C F835E6799B83473F870B4E7D9
Approved by:	RMCL	FEDERICA AZZIMONTI	14/7/2021 | 11:22 CEST	DocuSigned by: Federica Azzimonti Signer Name: Federica Azzimonti Signing Reason: I approve this do Signing Time: 14/7/2021 | 11:21 C F76117269A994B43A353A3F6C

* In case of NO, comment is mandatory