KURZPROTOKOLL
NOBLE002

Öffentlicher Titel	Anwendungsbeobachtung von HEMOBLAST Bellow während einer laparoskopischen Operation
Wissenschaftl. Titel	Post-market evaluation of HEMOBLAST Bellows performance and safety in laparoscopic abdominal, gynecological, and urological surgery
Kurztitel	NOBLE002
Studienart	multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie
Studienphase	nicht zutreffend
Erkrankung	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: sonstige Studien für Krebserkrankungen der weiblichen Geschlechtsorgane
Einschlusskriterien	- Pre-operative Inclusion Criteria: - 1. Patient is undergoing a non-emergent laparoscopic abdominal, gynecological, or urological surgery - 2. Patient is willing and able to give prior written informed consent for investigation participation; - 3. Patient is 18 years of age or older. - Intra-operative Inclusion Criteria - 1. Patient has one or more target bleeding sites (TBS) for which control of bleeding by conventional procedures is ineffective or impractical. - 2. The TBS(s) has been treated with HEMOBLASTTM Bellows as per their instructions for use.
Ausschlusskriterien	- Patient is pregnant, planning on becoming pregnant during the follow-up period, or actively breast-feeding; - Patient has a known sensitivity or allergy to bovine and/or porcine substance(s) or any other component(s) of the hemostatic agent; - Patient has religious or other objections to porcine, bovine, or human components; - Patient has any significant coagulation disorder; - Patient has any other contraindications, warnings, precautions of the Approved Instruction For Use of HEMOBLAST™ Bellows preventing his/ her inclusion - Patient is not appropriate for inclusion in the clinical trial, per the medical opinion of the Investigator
Alter	18 Jahre und älter
Prüfzentren	**Agaplesion Markus Krankenhaus** (Geschlossen) Wilhelm-Epstein-Straße 4 60431 Frankfurt am Main PD Dr. med. Marc Thill Tel: 069 95332228 Fax: 069 95332733 marc.thill@fdk.info
Sponsor	Biom'Up France SAS
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03873181 (primäres Register)