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
Sponsor	Biom'Up France SAS
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03873181 (primäres Register)