

KURZPROTOKOLL
NOBLE001

Öffentlicher Titel	Anwendungsbeobachtung von HEMOBLAST Bellow während einer offenen Operation
Wissenschaftl. Titel	Post-market evaluation of HEMOBLAST™ Bellows performance and safety in open gynecological, urological, ENT, head and neck, and vascular surgery
Kurztitel	NOBLE001
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	<ul style="list-style-type: none">- Pre-operative Inclusion Criteria:<ul style="list-style-type: none">- 1. Patient is undergoing a non-emergent open gynecological, urological, ENT, head and neck, or vascular 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<ul style="list-style-type: none">- 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 HEMOBLAST™ Bellows as per their instructions for use.
Ausschlusskriterien	<ul style="list-style-type: none">- 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 NCT03873168 (primäres Register)