

## **KURZPROTOKOLL NOBLE002**

<b>Öffentlicher Titel</b>	Anwendungsbeobachtung von HEMOBLAST Bellow während einer laparoskopischen Operation
<b>Wissenschaftl. Titel</b>	Post-market evaluation of HEMOBLAST Bellows performance and safety in laparoscopic abdominal, gynecological, and urological surgery
<b>Kurztitel</b>	NOBLE002
<b>Studienart</b>	multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie
<b>Studienphase</b>	nicht zutreffend
<b>Erkrankung</b>	Geschlechtsorgane: Krebserkrankungen der weiblichen Geschlechtsorgane: sonstige Studien für Krebserkrankungen der weiblichen Geschlechtsorgane
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Pre-operative Inclusion Criteria:<ul style="list-style-type: none"><li>1. Patient is undergoing a non-emergent laparoscopic abdominal, gynecological, or urological surgery</li><li>2. Patient is willing and able to give prior written informed consent for investigation participation;</li><li>3. Patient is 18 years of age or older.</li></ul></li><li>- Intra-operative Inclusion Criteria<ul style="list-style-type: none"><li>1. Patient has one or more target bleeding sites (TBS) for which control of bleeding by conventional procedures is ineffective or impractical.</li><li>2. The TBS(s) has been treated with HEMOBLAST™ Bellows as per their instructions for use.</li></ul></li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patient is pregnant, planning on becoming pregnant during the follow-up period, or actively breast-feeding;</li><li>- Patient has a known sensitivity or allergy to bovine and/or porcine substance(s) or any other component(s) of the hemostatic agent;</li><li>- Patient has religious or other objections to porcine, bovine, or human components;</li><li>- Patient has any significant coagulation disorder;</li><li>- Patient has any other contraindications, warnings, precautions of the Approved Instruction For Use of HEMOBLAST™ Bellows preventing his/ her inclusion</li><li>- Patient is not appropriate for inclusion in the clinical trial, per the medical opinion of the Investigator</li></ul>
<b>Alter</b>	18 Jahre und älter
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<b>Sponsor</b>	Biom'Up France SAS
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03873181 (primäres Register)