

**KURZPROTOKOLL**  
**NOBLE001**

|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Öffentlicher Titel</b>                        | Anwendungsbeobachtung von HEMOBLAST Bellow während einer offenen Operation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Wissenschaftl. Titel</b>                      | Post-market evaluation of HEMOBLAST™ Bellows performance and safety in open gynecological, urological, ENT, head and neck, and vascular surgery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Kurztitel</b>                                 | NOBLE001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <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 open gynecological, urological, ENT, head and neck, or vascular 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Prüfzentren</b>                               | <b>Agaplesion Markus Krankenhaus</b> (Geschlossen)<br>Wilhelm-Epstein-Straße 4<br>60431 Frankfurt am Main<br>PD Dr. med. Marc Thill<br>Tel: 069 95332228<br>Fax: 069 95332733<br><a href="mailto:marc.thill@fdk.info">marc.thill@fdk.info</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Sponsor</b>                                   | Biom'Up France SAS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT03873168 (primäres Register)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |