HemaClear® User Experience Form

Date: _____

General Information:

Procedure Date: _____ Physician Name: _____

Additional personnel involved : _____

Procedure description:

_____

_____

Hospital Name: _____

Country: _____ City: _____

HemaClear Model: _____

Production lot/batch #: _____ or

Product Sticker

Incident type: _____

_____

_____

Patient blood pressure at the beginning of procedure: _____ / _____ mmHg

Maximal blood pressure during procedure: _____ / _____ mmHg

Age: _____ BMI: _____ Gender: M / F

Limb circumference at occlusion site: _____cm

Limb length from toes/fingers till occlusion site:

_____cm

Occlusion site (positioning of the device on the limb):

_____

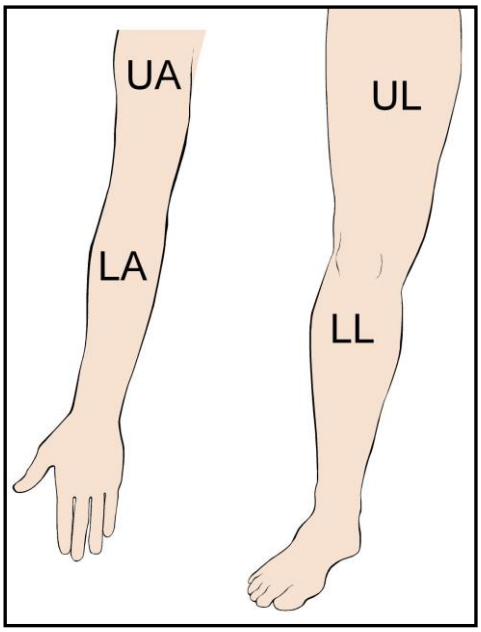
Type of anesthesia: _____

_____

_____

Procedure duration: _____ minutes

Tourniquet Time (total time): _____ minutes



Significan co-morbidities and chronic medications: _____

_____

Complaint Type (Mark all that apply):

Problem/Complaint	Question	Corrective/Suggestion
☐ Product malfunction	☐ Instructions not clear	☐ New product idea
☐ Faulty/Missing Parts	☐ General question	☐ Improvement
☐ Faulty/Missing Documentation	☐ Product functionality	
☐ Order Mismatch	☐ Tourniquet failure – why?	
☐ Delay in Delivery		
☐ Poor response/ Complaint		
☐ Occurrence Injury/ Death		

Additional Details and Follow up Infrormation:

_____

_____

_____

_____

_____

Contact information of reproting person: _____@_____ Tel: _____

Rep Name: _____ Company: _____ Tel: _____

Please email photos (or any other materials that cannot be provided by this form) to:

QA@hemaclear.com

Please note that a complete and detailed form is required for an effective case investigation.

For office use only:

Internal Case No.: _____ Date: _____ Signature: _____

Action taken: _____

_____

_____

_____

Customer Notification Date:_____