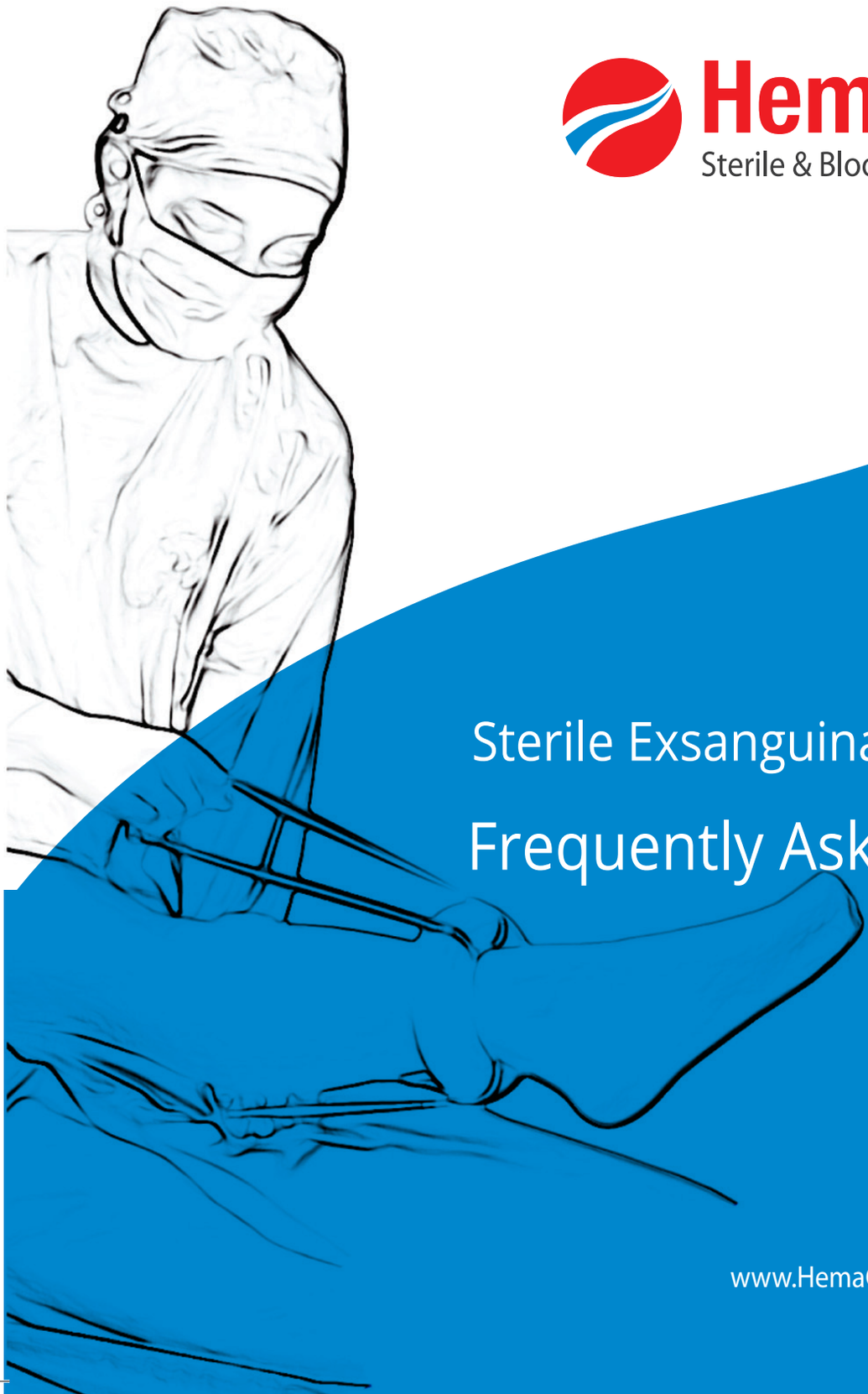

HemaClear®

Sterile & Bloodless Surgical Field

Sterile Exsanguination Tourniquet

Frequently Asked Questions

www.HemaClear.com

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
1	**What is HemaClear® and what is it made of?**	• HemaClear® is a Sterile Exsanguinating Occlusion device for surgical limb procedures - providing up to 95% exsanguination (blood removal) compared to ~67% with current techniques. • HemaClear® consists of an elastic silicone ring wrapped in a stockinet and 2 pulling straps with handles. • HemaClear® can be used without a power supply or compressed air source.	General
2	**How does HemaClear® work?**	• The surgeon places the HemaClear® on the patient's fingers or toes and pulls the handles proximally. The HemaClear® rolls up the patient's limb and the stockinet unrolls. • While rolling up the limb, the ring exerts pressure, which is greater than the patient's systolic blood pressure that shifts blood away from the limb, performing the exsanguinating (blood removal) function quickly and effectively. • When the ring reaches the occlusion site, the pulling motion is stopped. The ring exerts pressure on the limb at this position, blocking arterial blood flow into the limb and performing the occlusion function. • During the pulling motion over the limb, a stockinet unrolls and covers the limb up to the occlusion location, providing an instant sterile drape over the surgical field. The entire motion from fingers or toes to the occlusion site, takes less than 12 seconds significantly shortening prep time when compared to using a pneumatic tourniquet and Esmarch.	General
3	**What are the benefits of using HemaClear®?**	• Superior Exsanguination: The rolling action of the occlusive silicone ring pushes 95% of blood out of the limb, as opposed to 67% with the Esmarch bandage, and 45% when a limb elevation method is used. • **Creates a Sterile Field**: HemaClear® is a sterile, single use device that eliminates the need for contaminated reusable cuffs, thereby reducing the risk of infection. • **Increases Access to the Surgical Field**: Being 1" wide, the narrow profile and small footprint of the HemaClear® facilitates a larger and more accessible surgical field. • **Simple and Cost-Effective**: The easy application reduces preparation time and eliminates the need for tourniquet machines, contaminated reusable cuffs, and Esmarch Bandages. • **Reduces Post-Operative Complications**: The HemaClear® reduces the risks of post-operative complications such as DVT, Infections, Excessive Blood Loss, Tourniquet Related Pain, Tourniquet Related Skin Lesions ("burns"), and has the potential to reduce Post TKA Cognitive Deficit. • **Used in Around a Million Procedures Worldwide**: HemaClear® is FDA listed and CE marked. More than 20 published studies demonstrate the safety, reliability and clinical superiority of HemaClear® • **No Skin Injury** (vs. 20.7% for wide cuff) • **Diminished Tourniquet Pain** (vs. 39.7% wide cuff) • **No Tourniquet-Induced Nerve Damage** (vs. neuropraxia with a pneumatic tourniquet wide cuff)	General, Regulation/ Certification, FDA, CE

HemaClear® FREQUENTLY ASKED QUESTIONS

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4	**Does HemaClear® come in various sizes?**	HemaClear® comes in 4 primary Models/sizes intended for proximal limb placement (axilla and upper thigh) suitable for children and adults with limb circumferences ranging from 14cm - 85cm with maximum systolic blood pressure under 190 mm Hg. Additionally, there are 2 HemaClear® Models designed specifically for extremity placement (Model F for Forearm and Model A for Ankle). These are the HemaClear® Models currently available: • HemaClear® Small Pink • HemaClear® Medium Yellow, Red, Green • HemaClear® Large Brown, Orange, Blue • HemaClear® Extra-Large Black&White • HemaClear® Model F • HemaClear® Model A Each HemaClear® Model is designed for a specific limb circumference range, and a maximal systolic blood pressure.	General
5	**Can HemaClear® be reused?**	No. HemaClear® is a sterile single-use device that is removed by cutting when the procedure ends. Therefore, it cannot be re-used or re-sterilized.	General, Sterility
6	**How many HemaClear® units have been used worldwide?**	At present, around a million units have been used in orthopedic procedures globally.	General
7	**Is the HemaClear® Latex-free?**	Yes	Device composition, Sterility, Storage
8	**How should the HemaClear® be stored?**	The HemaClear® should be stored in a clean environment suitable for sterile medical products under the following conditions: • Temperature range: 7-28°C (45-83 °F) • Humidity: <60% RH	Device composition, Sterility, Storage
9	**What is the HemaClear® shelf life?**	3 years	Device composition, Sterility, Storage
10	**What happens after the HemaClear® expiration date has passed?**	• Do not use HemaClear® if the expiration date has passed. • After 3 years, the sterility of the device may be compromised. • For additional instructions regarding expired devices, please contact info@HemaClear.com.	Device composition, Sterility, Storage
11	**How is HemaClear® sterilized?**	HemaClear® is sterilized with Ethylene Oxide (EtO).	Device composition, Sterility, Storage
12	**Do the materials that HemaClear® is composed of contribute to its sterility?**	• HemaClear® components (silicon ring, stockinet, and pulling straps) are non-sterile prior to assembly, after which the HemaClear® undergoes a process of sterilization. • The product is shipped as a sterile unit.	Device composition, Sterility, Storage
13	**At the end of the surgical procedure, the surgeon cuts the silicone ring to remove the HemaClear® device. Is the inside of the silicone ring sterile?**	Yes. The inside of the silicone ring is sterile as is the entire HemaClear® device.	Device composition, Sterility, Storage

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
14	**What are contraindications for HemaClear®? Can the it be used on an infected limb or on patients with bone tumors?**	No. Please read the following Contraindications before using HemaClear®: • Do not use HemaClear® on patients with poor peripheral blood flow, edema, or Deep Vein Thrombosis (DVT). See the Wells Score System for likelihood of DVT. • Do not use HemaClear® if the limb is infected or with malignancy. • Do not apply HemaClear® directly on skin that is fragile or has significant lesions. • Use a sterile ace bandage to protect fragile skin before applying HemaClear®. • Do not leave HemaClear® on a patient's limb for more than 120 minutes. • Do not place HemaClear® directly over the ulnar nerve (at the elbow) or the peroneal nerve (at the proximal tibia).	Indications/ Contraindications
15	**Can HemaClear® be used on morbidly obese patients?**	Yes. The HemaClear® can be used on morbidly obese patients if the limb circumference does not exceed 85cm. Extra care must be taken with obese patients by monitoring their blood pressure. An obese patient has a great deal of blood brought from the larger limbs into central circulation. This 'auto-transfusion' can amount to more than 1.5 pints of blood from a single large leg. Pushing blood into central circulation very quickly within a few seconds, can cause a significant transient rise in blood pressure and increase the risk of tourniquet failure and bleeding. Some users have suggested the following 3-step solution: 1. Apply the HemaClear® device up to knee level. 2. Pause for 30-90 seconds, in order to enable the anesthesiologist to measure the blood pressure and, if need be, to make an adjustment. 3. Once the blood pressure is under control, the surgeon can continue pulling the straps to bring the device up to the upper thigh. This procedure will avoid the risk of exceeding the pre-set value of systolic blood pressure of 160 mm Hg for HemaClear® Model Extra Large (B&W).	Indications/ Contraindications
16	**Can HemaClear® be used on patients with fractures, and if so, which types and how?**	The use of HemaClear® on fractured limbs has been documented to be effective and safe in two published papers (below). • Axial traction should be in place while applying HemaClear® if the fractured limb is unstable. • If a limb has been fractured for 12-24 hours, there should be a full evaluation to rule out DVT prior to applying HemaClear®. • Open fractures are a relative contraindication and a surgeon should use his best judgment to balance risk vs. benefits. *Source 1: Use of a New Exsanguination Tourniquet in Internal Fixation of Distal Radius Fractures, Norman D, et al., "Techniques in Hand & Upper Extremity Surgery" Dec 2009, Vol.13, No.4.* *Source 2: Safety of using a novel device for creating a bloodless surgical field in pediatric limb fractures, Hous N, et al., Orthopedic Department B, Rambam Medical Center, Haifa, Israel. Presented at the 24th EFORT Conference in Nice France, 2008.*	Indications/ Contraindications

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
17	**Can HemaClear® be used for amputations?**	Yes, unless there is limb malignancy (see Contraindications). When amputation is performed on an ischemic limb due to peripheral vascular disease, diabetes, or other arterial occlusion diseases (e.g. Buerger's disease), it is important to verify that the tissue at the amputation location is viable and has a good blood supply.	Indications/ Contraindications
18	**Can HemaClear® be used in pediatric orthopedic procedures?**	Yes. HemaClear® is reported by many users to be extremely useful for pediatric limb surgery. • It overcomes difficulties associated with the short tapered anatomy, providing a large surgical field with excellent visibility. • The suitability of HemaClear® for children is defined by the limb circumference and not by age of the patient. • Since a child's thigh is usually wider than 24cm, HemaClear® Medium can be used for circumferences of 24cm-40cm • For small infants or narrow limbs with a circumference of 14cm-28cm the HemaClear® Small Pink is available.	Indications/ Contraindications
19	**What happens if the wrong HemaClear® Model (size) is selected for surgery?**	If the wrong HemaClear® Model (size) is used, the following may occur: • If too small a size is selected, it can be difficult to apply the device over the limb and may cause pain. • If too large a device is selected, this may result in partial exsanguination and incomplete occlusion, causing blood to leak under the ring ('tourniquet failure'). *Note: In case blood leakage does not stop, HemaClear® should be removed immediately.* It is important to work according to the Measurement Guidelines.	Indications/ Contraindications, Tourniquet failure, Tourniquet pain
20	**Is it possible to use HemaClear® on patients with varicose veins or thrombosis?**	HemaClear® can be used with varicose veins. In fact it is used by vascular surgeons during stripping or laser treatment of varicose veins. Superficial Venous Thrombosis (SVT) is a relative contraindication and surgeons should use their best judgment and verify that in addition to SVT there is no Deep Vein Thrombosis (DVT) present. *Source: http://www.prweb.com/releases/2012/3/prweb9340666.htm*	Indications/ Contraindications
21	**Can the HemaClear® be used for non-orthopedic limb procedures?**	Yes. • HemaClear® is routinely used in vascular access procedures such as brachiocephalic AV shunts. • The HemaClear® is routinely used in emergency care cases where the patient suffered from a laceration to the limb (especially hand and feet), when a bloodless field would prove helpful for quick and precise evaluation and closure of the laceration. Using the HemaClear® in such cases can avoid the necessity of opening an OR (pneumatic tourniquets are located only in the OR). • HemaClear® has been used in maxillofacial free flap graft procedures, as well as in various plastics procedures to limbs (reconstructions, etc.)	Indications/ Contraindications

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
22	**Do surgeons express a specific need for a bloodless/blood-free surgical field?**	Yes. • Blood-free surgery provides a clear surgical field, minimizes blood loss, gives the surgeon more control during the procedure, and shortens total OR time. • HemaClear® provides a bloodless surgical field that provides excellent visibility and reduces risk of DVT and pulmonary embolism. • HemaClear® is the first advancement in bloodless limb surgery technology since Henry Cushing introduced the Pneumatic Tourniquet in 1904.	Clinical
23	**Is there a risk of ischemia when a limb is exsanguinated for 2 hours?**	HemaClear® provides unprecedented exsanguination, eliminating almost entirely the chance of ischemia following up to 120 minutes in use. Limb tissues are far less susceptible to ischemia than are nerve cells (neurons) in the brain. Their metabolic needs are smaller and their ATP reserves, which come in the form of creatinine phosphate and oxygen attached to Myoglobin, are substantial. Many studies done on humans, as well as animal experiments, show that no irreversible change can be detected, as long as the tourniquet time does not exceed 2 hours (list of publications available upon request). The 2 hour time limit for the HemaClear® device corresponds to the standard of care for all existing surgical and trauma tourniquets.	Clinical, Tourniquet, Ischemia
24	**At the end of a procedure some surgeons gradually release pneumatic tourniquet pressure in steps. They do so to prevent a sudden gush to the heart of blood containing ischemia by-products from the limb. Does this present a problem when using HemaClear®?**	HemaClear®'s superb exsanguination (95%) reduces incidences of post-op DVT and pulmonary embolism. It also greatly reduces chances of ischemia by-products (e.g. potassium, acidity, and CO2) being released from the limb. Gradual release of pneumatic tourniquet pressure means that arterial blood enters the leg, while the veins are still blocked (venous occlusion). This has three negative effects: 1. Possible increased bleeding in the operation site due to increased venous pressure 2. A large volume of blood in the leg soaks all ischemia by-products from the extra-cellular space. 3. The tendency to lower the patient's blood pressure. Once the pneumatic tourniquet is finally completely deflated, the blood pool in the leg veins quickly re-enters the central circulation and the heart, actually worsening the load of cardiac-depressing chemicals on the patient's heart. *Note: We are not aware of any publication that supports the practice of gradual tourniquet release.* HemaClear®, on the other hand, exsanguinates far more effectively than other methods, resulting in no blood left behind. Thus, the ischemia by-products stay in the tissue and do not accumulate in the blood. • When the ring is cut and new blood enters the limb, ischemia by-products are gradually washed out with no sudden flooding of the central circulation and the heart. • Anesthesiologists feel that the drop in blood pressure upon releasing the HemaClear® is less common than that which occurs when using a pneumatic tourniquet device.	Clinical, Tourniquet release, Ischemia

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
25	**Is it possible to deal with the risk of inadvertent blood vessel damage when operating in a bloodless surgical field?**	In order to prevent such concerns, some surgeons perform homeostasis and suture the surgical incision after relieving the tourniquet pressure. Thus they ensure that no blood vessels have been harmed.	Clinical, Tourniquet release, Blood vessel damage, Bleeding
26	**Surgeons sometimes release tourniquet pressure during surgery to see if there are any "bleeders" before closing the surgical incision. How does HemaClear® address this type of situation?**	Experienced users report that benefits provided by HemaClear® make this a non-issue. • There is an ongoing debate among surgeons whether hemostasis, wound closure, and packing should be done before or after tourniquet release. This debate is independent of the type of arterial blocking used. • Generally, European surgeons' first close the surgical incision, whereas in the US many surgeons prefer to remove the tourniquet, perform additional hemostasis, and then close the incision. The literature shows that closing and packing prior to release is associated with less overall blood loss. However, with this approach there are occasional cases of bleeding into the wound and hematoma formation, which sometimes may require re-operation. It is up to the surgeon to decide which method to use. • Following surgeons' experience in checking for "bleeders" we recommend pulling the HemaClear® ring away from the limb with two towel clamps or two Army-Navy retractors. Once the surgeon is ready, the ring is allowed to return to its original location, thus re-occluding blood flow from the surgical site. This maneuver should only be done towards the end of surgery to avoid prolonged blood stasis distal to the HemaClear®. *Note: On the forearm it is possible for the surgeon to use his fingers to pull the HemaClear® away from the skin to provide temporary blood flow.*	Clinical, Tourniquet release, Blood vessel damage, Bleeding
27	**If a patient suffering from hypertension experiences blood pressure fluctuations during surgery, how should that be handled when using HemaClear®?**	The situation must be handled very carefully. Since HemaClear® pressure is factory calibrated and cannot be modified during surgery, it is the responsibility of the anesthesiologist to monitor blood pressure closely in order to avoid a rise in blood pressure. Although patients suffering from hypertension have a significant tendency for their blood pressure to shoot up, a rise in blood pressure can be seen in all patients. For patients who suffer from hypertension use the same 2 stage application approach applied with obese patients: • Pull the HemaClear® device up to knee level; pause for 30-60 seconds for morbidly obese patients, in order to allow the anesthesiologist to measure the blood pressure and, if needed, to adjust accordingly. • Once the blood pressure is under control, the surgeon can continue pulling the device to the upper thigh. This prevents exceeding HemaClear® pre-set pressure value.	Clinical, Hypertension

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
28	**What should be done with a hypotensive patient in order to avoid vascular risks at the moment of occlusion?**	Nothing needs to be done since there are no contraindications for using HemaClear® with hypotensive patients. HemaClear® has been used successfully to reanimate patients with very low blood pressure (shock) and even during cardiac arrest when used simultaneously on both legs (shifting blood from the limbs into central circulation increases the blood volume available and raises blood pressure).	Clinical, Hypertension
29	**Is it recommended to use HemaClear® in procedures where local anesthesia is applied? Also, should it be applied prior to or after injection of an anesthetic?**	It is possible to carry out short procedures such as carpal tunnel release and trigger finger with only local anesthesia infiltration of the skin. It is perhaps better to first inject the anesthetics and then apply the HemaClear® device from the tourniquet and OR time management point of view.	Clinical, Local anesthesia
30	**Can HemaClear® be used in conjunction with IVRA (Bier Block), and if so, how can that be done?**	Using HemaClear® for IVRA has been documented in literature, and is commonly used by surgeons. For further details on the use of HemaClear® for IVRA, please contact us at info@hemaclear.com.	Clinical, IVRA (Bier Block)
31	**When prepping a patient, are there specific differences in procedure when using HemaClear® vs. a Pneumatic Tourniquet?**	Applying HemaClear® is easier and faster than using a pneumatic tourniquet and no equipment is needed other than the sterile HemaClear® device. Intended occlusion location - groin or axilla: • Clean the limb and apply sterile liquid to the entire limb (up to the groin/axilla). • Sterile drapes should be placed on the proximal axilla/groin. The HemaClear® may be applied over the edge of the drape to create an overlapping section, to provide a recommended continuity of the sterile field. HemaClear® has its own built-in sterile stockinet, which is applied to the limb as part of the application process. There is no need for an additional sterile stockinet, unless preferred by the surgeon. HemaClear® can be applied over an impervious stockinet if there already is one on the foot. If a foot holder is being used, it is imperative not to try and apply the HemaClear® over the foot holder. In that case, release the foot, cover it with a sterile cover, apply the HemaClear®, and only then return the foot to the holder. Many HemaClear® users report that the entire motion from fingers or toes to the occlusion site, takes less than 12 seconds, shortening prep time by ~50% when compared to using a pneumatic tourniquet and Esmarch.	Device application, Preparation time
32	**What are the correct locations for placing the HemaClear® on a limb?**	The recommended locations for applying HemaClear® to or on a limb are: • **Thigh** – as proximal to the groin as possible. For procedures distal to the knee, HemaClear® may be placed at mid-thigh. • **Ankle** – up to 15cm (6″) proximal to the lateral malleolus. • **Upper Arm** – as close as possible to the axilla • **Forearm** – up to 10cm (4″) proximal to the wrist. For additional information, please refer to the HemaClear® User Guide.	Device application

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
33	**How long can HemaClear® remain on the limb?**	As with any other type of tourniquet, HemaClear® can remain on the limb for up to 120 minutes.	Device application, Tourniquet time
34	**How should tourniquet time be measured when using HemaClear®?**	Tourniquet time is measured from the time HemaClear® is applied until the ring is cut. Any watch may be used but a dedicated stop watch is preferred. Alternately, the HemaClear@ Pressure Calculator App has a dedicated tourniquet timer which is recommended.	Device application, Tourniquet time
35	**Why did HemaClear® slip a few centimeters distally, causing loss of pressure and bleeding to resume, when the correct Model was chosen according to systolic pressure and limb circumference?**	Even with a tapered leg, it is possible to prevent the HemaClear® from rolling back. Proper training for the correct use of HemaClear® should prevent the rolling back of the ring. • This is done by wrapping the straps around the limb immediately distal to the ring of the device with a loose knot, making it virtually impossible for the device to roll back, even on a tapered limb. • Clear visual instructions for proper application of the HemaClear® are available on the HemaClear® YouTube Channel https://www.youtube.com/channel/UCYUdKv4V5SxsSTXglqnbSAg *For additional information and questions regarding HemaClear® please contact info@HemaClear.com.*	Device application
36	**What is the best way to get HemaClear® over the heel?**	What is the best way to get HemaClearIn order to roll HemaClear® over the heel: • Place one handle facing the dorsum of the foot (top) and one handle facing the sole (bottom). Thus, the bottom handle assists in getting the ring over the heel. • Pull the leg upward with one hand while pulling the bottom strap downward and over the heel. It might require some effort.	Device application
37	**What are the common recommendations for using HemaClear® in foot and ankle procedures?**	When using HemaClear® for foot and ankle procedures the surgeon should place the device below the gastrocnemius muscle about 10-15 cm above the lateral malleolus. The recommended HemaClear® Model for foot and ankle procedures is the Model A. If the limb circumference at the intended occlusion location is larger than 32cm, or if the patient's foot is large (shoe size US14/EU47 or higher), it is recommended to use the HemaClear® Medium Orange in the same position (10-15 cm above the ankle).	Device application, Foot & Ankle
38	**The HemaClear® Model A may require some effort when rolling the device over the heel. How can this be made easier?**	Application of the Model A should be performed by 2 people. • When rolling over the heel, The person applying the HemaClear® should hold the upper straps steady 45 degrees to the heel, while at the same time leveraging the lower straps over the heel, similar to how a stocking or long socks are applied. • The assisting person should make sure that the limb is elevated and the foot is stabilized by firmly holding the ankle in one hand and the foot in the other. This allows the person applying the device the best leverage to easily roll the HemaClear® over the heel.	Device application, Foot & Ankle

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
39	**What is the purpose of the plastic conical cup included in the HemaClear® Model A and the HemaClear® Model F?**	The plastic parts in the Model A and Model F are application cups which are designed to allow easier application of the device over the toes and fingers respectively. • **Model F**: The application cup allows the Surgeon to apply the HemaClear® without an assistant (no need to hold the fingers together). • **Model A**: Since the silicone ring used is relatively stiff, it is difficult to stretch the device over the toes without the application cup. The application cup also protects the toes from getting caught or injured during the application process. The application cups should NOT be removed prior to applying the device.	Device application, Foot & Ankle
40	**How should the HemaClear® be applied when using a "thigh holder" during Arthroscopic knee procedures?**	As most thigh holders are none-sterile, using them in conjunction with the HemaClear® can be problematic. • When using a metal "U shaped" holder, it is possible to cover the holder with sterile drapes so that it can be placed safely within the sterile field. • The solution most surgeons prefer (especially for investigative arthroscopic procedures) is to use the HemaClear® in a non-sterile fashion, applying it after disinfection of the skin, but placing the ring proximal to the holder. Although this method reduces the available tourniquet time by ~5 minutes, surgeons report that having an absolutely bloodless field during these procedures is a huge benefit. When the hamstring ligament is being harvested, the HemaClear® prevents hematomas near the groin that are bothersome during postoperative recovery.	Device application, Arthroscopy
41	**How much pressure is applied by HemaClear®?**	Pressure (on the skin) exerted by the HemaClear® is comparable to pneumatic tourniquets at approximately 200 - 250 mm Hg for the upper limbs and 300 - 350 mm Hg for lower limbs. • The exact pressure depends on: A) The HemaClear® Model used; B) The limb circumference at the occlusion location; C) The distance of this site from the fingers or toes. • To find the exact pressure use the HemaClear® Pressure App (available free via Google Play) or alternatively, reference the Pressure Tables in the User Guide. • While pressure is constant, advantages of the HemaClear® narrow cuff are clear: • No skin injury (vs. 20.7% for wide cuff) • Diminished tourniquet pain (vs. 39.7% wide cuff) • No tourniquet-induced nerve damage (vs. neuropraxia with a pneumatic tourniquet wide cuff)	Pressure

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
42	**HemaClear® applies strong pressure to a small area. Can this pressure damage the limb?**	HemaClear® NARROW CUFF: In around a million procedures performed with the HemaClear® worldwide, there have been no reports of nerve or muscle damage caused to patient's limbs. • HemaClear® does not cause any adverse reactions to the skin. • No additional padding (webril and similar) is required when using the HemaClear®. • With HemaClear® there is no pinching, folding, or burning of the skin. • There are no adverse reactions resulting from the pressure of HemaClear® combined with the chemical reaction of antiseptic solutions applied to the skin. Pneumatic Tourniquet WIDE CUFF: It has been well documented that nerve damage occurs in ~1 in 4,200 patients when using the Pneumatic Tourniquet and/or Esmarch Bandage. • **Skin injury** - 20.7% (vs. no injury with HemaClear®) • **Tourniquet pain** – 39.7% (vs. diminished pain with HemaClear®) • **Neuropraxia** (vs. HemaClear® - no tourniquet-induced nerve damage) **Conclusion: HemaClear® is SAFE.**	Pressure, Clinical safety
43	**Tourniquet machines have built-in safety measures to prevent over-pressurization. What safety measures does HemaClear® offer?**	HemaClear® is accurately factory-calibrated, an important safety feature. • Prevents inadvertent over-pressurizing of the tourniquet. • Ensures that pressure will remain constant once HemaClear® is applied and will not vary mid-procedure.	Pressure, Safety
44	**What can be done to alleviate concerns that pressure cannot be regulated with HemaClear®?**	Pressure for the various HemaClear® devices is factory calibrated to match rated maximal systolic blood pressure: • Pediatric Models: 130/160/190 mm Hg • Medium and Large Models (Medium Yellow - 190 mm Hg and Brown - 190 mm Hg) • Extra Large Black&White Model: 160 mm Hg • Model F and Model A: 160 mm Hg HemaClear® exerts sufficient force on the patient's limb to provide safe and effective arterial blood flow occlusion, so long as the patient's systolic blood pressure does not exceed the rated product pressure. Hence, there is no need to regulate the pressure during the surgery. *Note: The practice of increasing pump pressure when blood escapes under the pneumatic tourniquet cuff without adequate exsanguination is risky due to clot formation in the blood vessels distal to the tourniquet. This can have SERIOUS consequences.*	Pressure

HemaClear® FREQUENTLY ASKED QUESTIONS

#	QUESTION	ANSWER	CATEGORY
45	**What happens if an operation lasts longer than 120 minutes and the surgeon is required to release and reapply the tourniquet?**	All tourniquets placed on a limb have a time limit of 2 hours. • If a procedure goes over 120 minutes, it is recommended to release the tourniquet and resume the blood supply to the limb for a minimum of 20 minutes (references available). • HemaClear® is no different in this respect. If surgery lasts over 120 minutes, the device should be removed by safely cutting the silicone ring. • After a proper duration of limb reperfusion, a second HemaClear® can be applied. HemaClear® can be placed safely over the surgical incision as it is a sterile device. While doing so, the surgical site should be protected by covering it with a sterile pad.	Pressure, Tourniquet time
46	**A pneumatic cuff allows for easy pressure release for reperfusion after 120 minutes. Is this possible with HemaClear®?**	When using HemaClear®: • The device can be removed after 90-120 minutes. • A new HemaClear® can be applied once reperfusion has occurred. • There are significant issues surrounding the practice of temporary tourniquet release for reperfusion. • A serious problem occurs when deflating and inflating a pneumatic tourniquet without adequate exsanguination prior to re-inflation. • A significant amount of blood is trapped in the vessels distal to the tourniquet. • This leads to intravascular clotting and to pulmonary and cerebral embolization. *Source: Cerebral Microembolism Diagnosed by Transcranial Doppler during Total Knee Arthroplasty, Sulek CA, et. al.*	Clinical reperfusion, Tourniquet release
47	**Will a patient's skin be damaged while removing the HemaClear®? How can this be prevented?**	A sterile plastic "Protective Cutting Card" is included in the packaging of every HemaClear® device. • One side of the cutting card has a triangular wedge shape. • When it is time for the HemaClear® to be removed, the wedge side of the cutting card should be inserted under the HemaClear®, distally to the patient, between the stockinet and the HemaClear® ring. • It is possible to use the left over application strap to pull the ring proximally to the patient in order to ease the insertion of the card. • Once the protective card is firmly placed under the HemaClear® ring, it is safe to cut and remove the HemaClear® with a scalpel in small gentle motions. *Note: It is also possible to slide a surgical tool such as an Army-Navy retractor under to HemaClear® to protect the skin from being cut.* • Dr. Mark Dodson has developed a stainless steel protective accessory named the "Dodson Extremity Skin Saver," designed to help protect the patient's skin when removing a disposable tourniquet. *It is available at: www.Innomed.net/general_orthopedic.htm#DodsonSkinSaverGen* • Please refer to the User Guide and the application videos on the HemaClear® YouTube channels for precise instructions. *For additional instructions regarding this matter, please contact info@HemaClear.com*	Removing HemaClear®

#	QUESTION	ANSWER	CATEGORY
48	**A common convention states that wider cuffs are better than narrow cuffs. HemaClear® is ultra-narrow. Does this pose a problem?**	Advantages of the HemaClear® narrow cuff are clear: • Superior exsanguinations and occlusion • No skin injury (vs. 20.7% for wide cuff) • Diminished tourniquet pain (vs. 39.7% wide cuff) • No tourniquet-induced nerve damage (vs. neuropraxia with a pneumatic tourniquet wide cuff) In order to stop arterial blood flow, it is sufficient to occlude the artery over a short (few mm) segment, which is efficiently achieved by HemaClear®. Compressing a much larger volume of tissue in order to block the flow in an artery is definitely not necessary and may actually be detrimental. While the skin pressure needed to occlude blood flow with a wide cuff is similar to that used by a narrow one, the fact that a greater area is exposed to external tissue compression is worrisome. Furthermore, the wide cuff elongates the nerves, which may cause telescoping and damage. According to information published in JBJS, nerve related injury with a wide cuff is 1:4200, while none has been seen with the narrow HemaClear® thus far. *Source: Surgical Tourniquets in Orthopedics, Gavriely N, Journal of Bone & Joint Surgery, MD, DSc, Vol. 92-A, Number 5, May 2010.*	Narrow vs. wide cuff

HemaClear® Products including Protective Card and Measuring Tape

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