TWENTY 20 Healthcare

adapting to change, alternative thinking
for medical equipment and supplies

Collaclot

Collaclot™ Questions and Answers

What is the active ingredient in Collaclot™?

The active ingredient is the collagen binding receptors in cells and in the blood which bind the protein and cells. It provides a scaffold for blood to start clotting.

Is there any risk of allergens being present in the product?

Collaclot™ is made from chicken collagen. Poultry has significantly less of an allergenicity in humans. Our intensive diafiltration process removes the vast majority of any allergens.

What makes it better than other widely used haemostatics?

Collaclot™ clots blood, as opposed to stopping bleeding due to pressure being put on the wound. It also works in extreme conditions, especially Antarctic situations. It is also fully biodegradable.

Is its efficacy affected by external temperatures, and what are the storage requirements in terms of temperature range?

No it is not affected by external temperatures, this can be used in temperatures from -95°C to +55°C, unlike the current products. Collaclot™ relishes in cold weather, as vasoconstriction occurs and therefore arteries are reduced and platelets are not affected.

Do you need to apply direct pressure after application?

It is advised to apply direct pressure on to the product until bleeding stops, however, you can use additional assistance such as a tourniquet and bandaging the haemostatic sponge in place in order to be able to deal with multiple casualties.

How does Collaclot™ work?

Collaclot™ works by activating the primary and secondary haemostatis (this is cellular and blood protein systems for clotting blood, working with your natural blood cascade to form a blood clot).

Does Collaclot ™need to be removed after use?

Collagen is a biodegradable product and can be left in the body, however, if the product has been used outside of a medical theatre, it is recommended to remove this from the body due to dust or dirt particles.

Are there any documented re-bleeds following use of Collaclot™ in evaluations?

Our independent trials have never registered a rebleed. There is extensive documentation out on competitors' products that are the current leading haemostats, that shows a high percentage of rebleeds were observed during similar trials.

How robust is the product? Does it required to be protected from damage before use?

It is only necessary to protect the product if it is in a combat situation.

If the product is broken up in the packaging can it still be used and will it be as clinically effective?

Yes, this product is still effective regardless of being broken in the packet.

What different formats does the product come in?

The product comes in two current formats – 3 x 3cm and 10 x 7.5cm, but can be torn to size if required.

Are there any contra-indications for use?

We are not aware of any contra-indications. In extreme cases, an EpiPen which would be carried around by a medic, would be used if any allergic reaction occurs.

On applying the product, if bleeding continues should I add more Collaclot™?

We have done extensive testing to believe that one sponge should deal with one bleed. However, if there are multiple bleeds or multiple limb loss then more than one product would be necessary.

What is the shelf life of the product?

The shelf life is 5 years.

Is this product vegan friendly?

It is vegan friendly as it can be removed from the wound, however the product is derived from animal tissue, so the product itself is not vegan friendly. It is, however, religiously friendly and can therefore be made into Halal and Kosher methods. You cannot make a vegan friendly product at this price and this effective, from a plant-based product.

Are there any potential issues with the product being absorbed into the bloodstream?

Unlike data becoming available with both Chitosan and Kaolin, the bloodstream can cope with collagen and the body has already dealt with collagen in every injury that the body has already had and has been absorbed easily.

Can the product be used internally?

There are multiple used for a collagen sponge, with internal injuries such as liver lacerations etc. However, this will need to be approved separately for each application and is pending approval.

Can the product be used on injuries involving access to the digestive tract – ie can it be ingested safely?

Yes it can be eaten with no adverse effects. We actually have products in the making specifically for this particular application in a liquid form, for digestive tract injuries – this is still in the R&D stage.

Are there any risks associated with using large amounts of the product on a single patient?

It is extremely unlikely that there are any risks associated and we haven't come across any at this particular stage.

If the packaging is already open, can the product still be used?

We would not recommend it to be used if already open as it is a sterile product. However, in extreme circumstances there would be little reason not to use it. The only risk is the introduction of bacteria into the wound.

Is there any exothermic reaction when the product is used?

No there are no exothermic reactions.

What activates the product?

Contact with blood.

Does the product need to be packed into the wound, or just placed to work?

This depends on the size of the wound. If you are dealing with an arterial bleed then it needs to be packed into the wound as close as possible. If you cannot easily pack into the wound, you can place the sponge on top.

Does the product need to be placed exactly on to the point of bleeding in order to work?

It is not essential to have the product placed exactly on the point of bleeding. Getting it as close as possible will speed up the clotting process. The product works when in the blood pool. Unlike the leading UK competitor, if this product is placed directly at the point of bleeding, it won't dislodge the clot when being removed, which is the main cause of re-bleeding.

Is the product effective on arterial bleeds?

Yes this product is designed from the worst trauma bleed (arterial bleed) downwards.

Can the product be used if it gets wet / in water environments?

In a rainy or wet environment, providing it is put into the wound quickly, it will be effective. This is again a very quick implemented product.

Is the packaging easy to open with wet/slippery hands?

We have taken note of the competitors' multiple openings and our packing company advice, and the packaging has multiple tear indentations.

On placing the product, does it matter what orientation it is in?

No it doesn't, it is collagen so it will work. However, for a quicker clot it is recommended that the perforated side is facing down towards the wound. The packaging is designed and instructions are clear on how to administer – but overall will have the same effect.

Can the product be used in tortuous wounds?

Yes it is fully effective in tortuous wounds.

How long can the product be left in the wound before requiring removal?

The sponge is fully biodegradable and it is collagen so wouldn't do any harm if left in the wound. However, we would recommend removable as the wound is likely to be dirty already.

Is any debridement required after use?

Collagen is a natural product in the body, so it can be absorbed. Although, debridement is recommended for dirt removal. Data has shown that both Kaolin and Chitosan in competitor's products have been left in the wound and go into vital organs – this would not be an issue with collagen or the Collaclot™ product.

Do surgeons need to be informed if Collaclot™ has been used on the patient on handover?

Yes they should be informed and as much information is passed on to the next point of care.

Are there any medications/medical products that cannot be used on a patient after Collaclot use?

No there are no interactions with other medicines.

Can the product be used in the presence of large amounts of blood, or does it need removing from the wound first?

The only reason why we suggest you remove blood from the wound, is so you can see where the point of bleed is, but it will work if put into the pool of blood.

What are the risks and dangers of embolization with Collaclot™?

Taking advice from vascular surgeons, there are no risks or dangers. With competitor's products, the product does not form a plug and relies on additional good flesh. When our product is removed, there is no need to cut away any of the good flesh or artery, which allows a vascular surgeon to repair the artery within a 4 hour period.

Can Collaclot ™be used on animals?

Collaclot™ is designed for use on animals. It is made to ISO13485 standards.

Is its use affected by altitude?

The red blood cells and platelets are increased at altitude, which actually increases the clotting process. So it is effected, but in a positive way.

Does adding more Collaclot™ to a wound make it work better?

Collaclot™ has been manufactured to deal effectively with trauma arterial bleeding with the size of the product available. However, with multiple bleeds, we would suggest using more than one. Unlike competitors, our sponge isn't impregnated or sprinkled with collagen – the whole structure is collagen, so no more collagen is needed to make a better effect.

Is this a religiously acceptable product?

The manufacturer can make bespoke Halal and Kosher haemostatic sponges on request of the country that requires them and it is available to be manufactured in a variety of religiously friendly versions.

Is there any risk if I get Collaclot™ in my eye?

No risk, as it is collagen. The lens of the eye is actually a form of transparent collagen.