


Powder for absorption and removal of wound exudate for use on wounds where healing proves difficult.

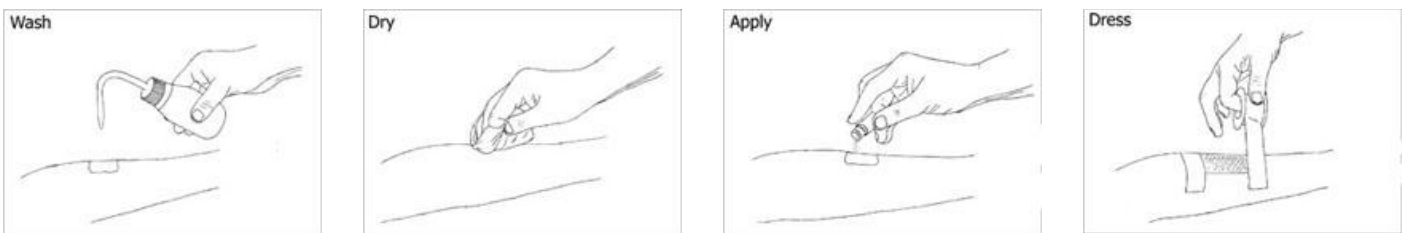
	<p>DO NOT:</p> <ul style="list-style-type: none"> • Use if the bottle is damaged. • Use if the shelf life has expired (see bottle). • Expose the bottle to a direct heat source. • Combine SertaSil® with any other products or therapies which may exert an effect directly on the wound. 	<p>DO:</p> <ul style="list-style-type: none"> ✓ Keep SertaSil® out of the reach and sight of children. ✓ Store refrigerated (2°C to 10°C). ✓ Use within 15 days of first opening. ✓ Recycle both the bottle (HDPE) and cardboard box according to local regulations.
<p>Manufacturer: Willingsford Ltd., NFEC, Rushington Business Park, Chapel Lane, Southampton, SO40 9LA, UK. contact@willingsford.com</p>		

INDICATED FOR:

- | | | | |
|-------------------|--------------------|-------------------|-------------------|
| ✓ Infected wounds | ✓ Chronic wounds | ✓ Surgical wounds | ✓ Physical trauma |
| ✓ Necrotic wounds | ✓ Open abscesses | ✓ Burns | ✓ Pressure ulcers |
| ✓ Lacerations | ✓ Degloving wounds | ✓ Puncture wounds | |

Indicted for: Equines, Canines, Felines, Rabbits, Birds and other Animals. Limited experience with Reptiles and Amphibians.

GUIDANCE FOR PREPARATION, APPLICATION, USE AND AFTER-USE



PROCEDURE

Please read these instructions in full before applying SertaSil®.

- ✚ Indicates that the specific product can be obtained from a pharmacy.
- ✖ Indicates that the specific ingredient or product is to be avoided, e.g. in case it is suggested to you at the pharmacy.

1. Assess the wound

If you are in doubt, or the wound is very deep, large and/or contains exposed bone, tendon, access to cavities or ruptured sutures, SertaSil® may prove effective, but the wound should first be assessed by a veterinarian.

Do not apply SertaSil® but consult a veterinarian if you suspect any other complication deeper in the wound such as:

- The reddened area surrounding the wound is extensive or increasing in size.
- There may be a broken or chipped bone or a foreign body, for example a piece of grit or small thorn.
- There could be a cyst, abscess or tumour.

SertaSil® is not effective on completely dry surfaces.

2. Create a clean environment

Wash your hands. Place an absorbent pad under the wounded area, if possible. Put on clean single use gloves. Always change gloves after cleaning the wound, before applying SertaSil®.

3. Wound preparation

Debride the wound, i.e. remove dirt, pus, dead tissue, slough, any very old scabs or other evidently inappropriate material.

4. Clean the wound

The preferable use of tap water and a wash-bottle (or alternatively a large syringe) will allow a good cleaning pressure without harming the wound bed. A saline solution ✚,

may be used to wash the wound instead. A wash bottle ✚ can be easily obtained from Willingsford Ltd., a pharmacy or via the internet.

If the wound is full of pus and dead tissue that you cannot remove by washing as above, a 3% hydrogen peroxide (H₂O₂) solution ✚ can be used. Apply, allow for froth creation and wash off with water. Do not leave on for longer than 20-30 seconds, and then wash off with water. Cease repeating application once no froth is created, indicating a clean wound. H₂O₂ should not be used in very deep or large wounds as there is a risk of gas embolism.

DO NOT USE antiseptics such as Chlorhexidine, silver, Polihexanide, Octenidine, iodine or PHMB ✖.

5. Dry the wound gently

Using a dry lint-free swab (gauze pad) ✚ dab the wound dry.

6. Apply the primary dressing - SertaSil®

Sprinkle SertaSil® in an even layer 1-3 mm thick, directly onto the entire wound surface - the area that is exposed to the air and accessible from the opening in the skin. This includes the visible area, all crevices, beneath loose flaps of skin and any undermined areas, all sides of the wound and all surfaces lining any tunnelling such as tracts, sinuses, fistulas etc..

Cover the wound edges well, extending to an area 2-5mm from the wound edge, onto the surface of the unbroken skin surrounding the wound opening.

If necessary, gently use a swab or your gloved finger to ensure all areas are covered with SertaSil®, including the underside of any affected flaps of skin, by dabbing upwards.

Sinus walls and cavities can be applied by depositing SertaSil® on the flat handle of a wound probe or a spoon, carrying it down the tunnel and depositing it in the desired area. If the tunnel is large, it is possible to use a clean gloved little finger to ensure the distribution of SertaSil® at the bottom and walls.

If the wound is on a vertical surface, e.g. on the head or leg, apply a 1-3mm thick layer of SertaSil® the size of the wound, plus an extra 5mm perimeter directly onto a dressing (see section 7). Place it directly over the wound and fix it there using sticking plaster tape.

7. Apply a secondary dressing

To keep the SertaSil® layer in place on the wound, cover it with a very light, dry and highly permeable dressing. This allows the wound to 'breathe' - access to air promotes an environment favourable to healing and permits evaporation.

We recommend 4 options:

- A. 4-ply lint free swab (a thin gauze pad) + secured with sticking plaster tape. Apply the pad directly on top of the SertaSil® after making extra sure that the entire area of broken skin is well covered with SertaSil®.
- B. 2-ply lint free swab fastened with gauze roll, tubular gauze, or surgical stockinette (see Section 8 Securing the dressing).
- C. Contact layer dressing (see this section below) covered with 2-ply gauze and secured with sticking plaster tape.
- D. Contact layer dressing fastened with gauze roll, tubular gauze or surgical stockinette.

The contact layer dressing must be paper thin, dry, non-impregnated and of an open mesh that makes it highly permeable. Examples of suitable contact layer dressings are N-A Ultra (non-adhesive), Mepitel, Adaptic Touch, Atrauman Silicone (slight auto-adhesive) +. Take care when choosing a contact layer dressing. Many such dressings are impregnated ✘ with substances such as paraffin, lipido-colloids, triglycerides (fatty acids), petrolatum, ointment, honey, iodine etc. **THESE MUST BE AVOIDED** because SertaSil® cannot work if used in combination with other products that exert any effect directly on the wound.

If the dressing causes a reaction, i.e. redness and/or dryness, do not use it. Instead, use option A or B.

8. Securing the Dressing

Options A & C:

Fasten the secondary dressing using sticking plaster tape. The tape should not pass over the wound area as that may block evaporation and access to air; it should run only over areas with healthy skin underneath (e.g. along the borders of the dressing). Suitable tapes differ between places on the body as some places nearly don't move and others undergo strain. Also some individuals are more accepting of wearing a dressing than others. Examples of tapes that seek to reduce allergy(sensitivity), pain and pulling out fur when removed are Leukosilk and Urgofix +.

Options B & D:

Depending on the location of the wound, e.g. abdomen or legs, it can be preferable to cover the gauze pad (Option B) or the contact layer dressing (Option D) lightly using very open-weave gauze roll + and fasten this with tape. For other locations, cover lightly with a layer of open woven tubular gauze or very thin open woven surgical stockinette +.

If the skin is so fragile that application of any adhesive to keep the dressing in place is likely to break the skin upon removal, use only tubular gauze/stockinette if possible in that location. Alternatively, leave the SertaSil® layer uncovered. See the section on Difficult-to-Dress Areas.

Remember:

- Prevent the animal from applying pressure to the wound surface, e.g. by resting on the wounded area.

- Avoid blocking the access of air, e.g. by allowing the animal to snug up placing the wound up against a pillow or blanket.
- Minimise the time SertaSil® is outside the refrigerator.

WOUNDS IN DIFFICULT-TO-DRESS AREAS

If necessary, SertaSil® can be used on a wound without a dressing or bandage covering it. Follow the standard preparation and cleaning procedures as described above, then dab as much SertaSil® onto the wound as will stick. Because there is no covering, SertaSil® may need to be reapplied more frequently as the SertaSil® layer will be at risk of being worn off.

FREQUENCY OF APPLICATION

Best results will be obtained by applying SertaSil® once every day until all dead tissue and infection is gone. This will be seen as the amount of cloudy liquid secreted by the wound being very low and the wound no longer looking dirty, or caked on the surface when the dressing is removed.

If a dirty, caked and/or very wet appearance reappears at a later stage in the healing process, use SertaSil® as before until the wound is clean. One application is usually sufficient.

PROFUSELY EXUDING ('WEEPING') WOUNDS

If the wound is oozing uncontrollably, the most effective way to use SertaSil® is to follow the standard preparation, application and dressing procedures described above. When the dressing is completely *soaked*, change the SertaSil® and secondary dressing. This may have to be done 2 to 3 times, with increasing intervals between changes, for the first 24 hours, for example after 4, 8 and then 12 hours.

When the SertaSil® no longer has a soaked appearance, within 8 to 12 hours, continue the use of SertaSil® as described under Frequency of Application.

DRESSING CHANGES

Follow these steps:

- i) Remove all dressings as gently as possible. Proceed slowly and cautiously without jerking or tearing.
- ii) Gently clean the wound surface as described in section 4.
- iii) If SertaSil® has been applied correctly, i.e. covering the entire wound surface and edges, the covering dressing will not stick to the newly formed cells in the wound bed. Should it seem lightly stuck, the substance adhering to the covering dressing is usually of a gel-like consistency. This contains waste from the area beneath and surrounding the wound opening. It needs to be removed from the wound – see next step.
- iv) Very gently, remove as much slough, i.e. loose and/or yellow or foul looking material as possible. This can be done by wiping very gently e.g. with a clean swab moistened with water. Take care not to harm new tissue and newly formed cells that may be forming in the wound bed but may still not be visible to the naked eye.
- v) Wash the wound with water, applying a good cleaning pressure by the use of – preferably – a wash-bottle, or alternatively a syringe, to clean out the old SertaSil® along with any yellow or foul looking matter on the wound or wound edges. The water pressure allows effective cleaning of all corners and crevices but take care not to disturb any newly formed tissue in the wound bed, **OR**
- vi) If the wound cannot be thoroughly washed, wipe it very gently using a moistened lint free swab. In these circumstances it is preferable to leave a tiny bit of old SertaSil® in the wound to avoid disrupting any tissue that is

forming. SertaSil® does not enter the body and is not harmful.

vii) Finally, repeat the application of SertaSil® as described in sections 5, 6 and 7.

Provided new forming cells are undamaged, the better the wound is cleaned of unwanted matter, the quicker the healing will progress.

If the wound contains substantial amounts of necrosis (dead tissue), slough, pus or other matter, seek advice from a veterinarian who will use the guidance in the section Dressing changes on Complicated, Non-healing, Chronic wounds and/or wounds with an Extended Infiltration Area.

DRESSING CHANGES ON COMPLICATED, NON-HEALING, CHRONIC WOUNDS AND/OR WOUNDS WITH AN EXTENDED INFILTRATION AREA

Debride as much as possible

If difficult to remove necrotic tissue without risk of causing damage, apply SertaSil® and, typically, the necrotic tissue will be softer the following day and can be lifted out or removed using sharp debridement. Loose, wet slough can be removed using a lint-free swab.

Complicated wounds will use the wound surface as the place to deposit the waste that is being cleared out from the deep and surrounding penumbral areas. This waste will typically, and unless the wound is very deep, be stuck to the secondary dressing and automatically be removed when the secondary dressing is gently removed. Usually, this waste will either be soft yellow slough or of a soft gel-like nature. Dependent on the circumstances in the surrounding tissue and penumbral area (e.g. deep tissue infiltration or partial necrosis or old blood residue (e.g. caused by prior packing dressings) it can, but does not necessarily, have a mucky appearance. Remove as much as absolutely possible of any unwanted matter.

If necessary, 3% hydrogen peroxide (H₂O₂) can be used as a light debrider.

Clean the wound thoroughly using sensibly pressurised water.

Using a wash-bottle to apply a good cleaning pressure will facilitate the cleaning of all corners, crevices, undermined areas, tunnels, etc of the wound without causing damage to the simultaneously granulating tissue in the wound.

Expectations to wounds in need of prolonged SertaSil® therapy.

SertaSil® is frequently able to provoke the re-initiation of the healing process in wounds that have not responded to any healing support for prolonged periods of time or in which the process is spinning out of control.

This lack of willingness to heal is frequently caused by complicating factors hidden outside our view, i.e. in the at times extensive penumbral area. While the penumbral area is being cleared and sorted, the wound will continue to deposit fresh slough and waste on the surface for days. Simultaneously, the wound will, typically, be granulating in some areas. The optimal way to help the wound get rid of the slough and waste without damaging the new granulation tissue, is by giving it a proper shower. Is this not possible, a similar experience can be achieved by the use of a wash-bottle supplying plenty of water with a reasonable pressure.

Expectations for wounds in need of prolonged SertaSil® therapy – and signs indicating the wound is clean

As the wound progresses over days, the amount of waste material on the wound surface waiting to be removed at dressing changes will reduce. The gel-like structure of the waste material on the surface will change into a suspension-like structure (micro-granules in liquid) and the colour will change into a beige to off-white colour. This is a sign that the penumbral area is clean and that the entire area is on the course to healing. This can also manifest itself as the entirety of the, limited, exudate being of a healthy transparent nature (lymphatic fluid). Or the wound may quite simply show a healthy pink granulating surface with epithelialisation. These events are markers for discontinuation of the use of SertaSil®.

DURATION OF USE

Once the wound has reached a clean, granulating state, application of SertaSil® should cease as SertaSil® enables the body's own healing process to take over. Continued use of SertaSil® is no longer necessary.

This clean stage is usually reached within 1 to 5 days of first application.

A clean, granulating wound will be red, usually with new blood supply visible as red buds, and clean, pale white tissue on top and/or in between. The edges will be whitish and the surface shiny and moist. There should be no cloudy yellow, greenish, bluish or brownish colour and no discharge from the wound.

Take care not to mistake lymphatic fluid (a yellowish transparent odourless discharge) for pus (cloudy yellow/orange/green/brown and possibly foul-smelling). Lymphatic fluid is a healthy wound response and will quickly diminish by itself without the use of SertaSil®.

Dressed wounds - discontinuation

The healing wound will typically have a granulating wound bed and epithelialising wound edges. This means, the healing wound will typically have a moist and healthy pink/red structured surface appearance and white - not grey or red - healthy looking edges. Edges should not be wet, only moist. In a shallow wound, connective tissue with new blood supply will usually be visible as red buds in the wound bed. This is highly desirable; the wound should now be left undisturbed for healing to progress.

The wound will normally start re-building from the bottom with new connective tissue and subsequently contract from the edges. New skin formation will be visible as pale whitish isles in and on the wound bed as well as moving in from the wound edges.

These features may appear in different areas of the wound on different days. If one part of the wound is clean and covered with red buds or white isles, only apply SertaSil® to the still struggling area. If this is not possible, cover the entire wound with SertaSil® until repetition of the process cleans it completely.

Non-dressed wounds - discontinuation

If the SertaSil® was not covered with a dressing, the clean wound will typically have a dry, pale red, flexible surface, white healthy edges but it will likely be without a traditional scab.

Do not touch this crisp-looking, flexible wound: leave the final SertaSil® layer on the wound and avoid it getting wet. Leave the wound undisturbed. The surface will gradually change into a healed surface.

In some cases, the clean, non-dressed wound may have an appearance similar to a clean wound which had been dressed.

Complicated, Non-healing, Chronic wounds and/or wounds with an Extended Infiltration area and/or wounds in need of prolonged SertaSil® therapy – discontinuation

Continue the use of SertaSil® for as long as the wound continues to bring necrosis, pus and other waste material forward and depositing it on the surface where it will typically stick to the secondary dressing. Upon removal of the waste, the surface underneath will likely be granulating. Once the waste deposits turn into an off-white to beige colour and from a gel-like consistency into a suspension-like nature (tiny granules in liquid), the wound, including the penumbral area, has reached a clean state and SertaSil® can be discontinued. In other types of wounds, the sign for discontinuation is simply that there is no more excess exudate or that the limited exudate is light-yellowish transparent (lymph). In the latter case, the granulation of the visible wound area will usually be quite advanced.

AFTER DISCONTINUATION OF SERTASIL® THERAPY

When SertaSil® therapy ceases, the wound should now be left undisturbed as newly generated cells and tissue remain fragile. The micro-environmental conditions that have been created in the wound now favour healing and must be conserved. Similar to the conditions on the skin itself, this microenvironment needs access to the air. Dressings subsequently used must therefore be fully permeable and allow air to reach the wound. Any adhesion to the healing wound bed must be avoided. A paper thin, atraumatic, open mesh, fully permeable contact layer dressing, e.g. N-A Ultra, with a 2-ply gauze on top will provide these conditions +. The procedure is similar to that used on top of the SertaSil® layer - but without the SertaSil®. Change the dressing every week or two until full closure. If the dressing gets wet or soiled, change it without touching or disturbing the wound. Should the wound get wet, wash, dab dry and apply a clean dressing.

SERTASIL® WITH PROTECTIVE DRESSINGS

Generally, dressings which prevent air circulation to the wound are not recommended. If a protective dressing is necessary, the SertaSil® layer should be covered with a highly absorbent, plain dressing (e.g. Zetuvit Plus; Kerrafoam; Tegaderm) or a standard absorbent, plain foam dressing (e.g. Allevyn), + without any active components (e.g. silver; PHMB, iodine, octinedine) ✗. The protective material can be placed on top of this secondary dressing. This dressing can be left in place for 1-2 days. Follow the recommended procedure for the chosen type of secondary dressing.

PRECAUTIONS

SertaSil® is For External Use Only

Do not eat.

Keep SertaSil® out of the eyes. Should that occur, immediately wash out the eye(s) with plenty of water or mild salt solution and seek veterinary assistance.

The components of SertaSil® have no known toxicity as used in SertaSil®. No adverse reactions or allergic reactions have been observed or are expected. Nevertheless, avoid inhalation and exposure to the eyes.

The ingredients of SertaSil® are not regulated by the International Doping Agency or FEI.

SertaSil® is not associated with any withholding times.

Apply minimally on exposed nerve bundles. If bundles of nerve fibres (called fascicles) are present in the wound - as

soft, white, thin tube-like structures - limit the application of SertaSil® directly onto these to a very thin layer as excessive removal of moisture may cause irritation of the nerves. In case this happens, wash off the SertaSil® with tap water and any pain will quickly subside.

OTHER INFORMATION

SertaSil® is not absorbed by the body.

SertaSil® can be removed by simple irrigation with water.

Antibiotics can be administered in conjunction with SertaSil®. Upon commencement and completion of a course of antibiotics, expect a 24-48 hours delay or setback in the wound healing process. This arises for wounds actively receiving SertaSil®, and wounds continuing the healing process after SertaSil® therapy has ended.

DO NOT combine SertaSil® with any other treatments or therapies applied directly to the wound.

These may impact the actions of SertaSil®. Examples of topical (i.e. applied on top of the wound) treatments to avoid ✗ are:

- Honey
- Silver
- Collagen
- Gelling agents
- Iodine
- PHMB
- Gels
- Polihexanide
- Octenedine
- Topical Negative Pressure
- Topical antibiotics - as ointment, cream, gel and powder.
- Absorbent dressings which are impermeable to air ('occlusive') e.g. alginates, foams, etc.

DO NOT use *impregnated* contact layer dressings with substances such as paraffin, lipido-colloids, triglycerides (fatty acids), petrolatum, ointment, silver, iodine, honey etc. ✗

DO NOT use Chlorhexidine, Polihexanide or PHMB ✗. These are toxic and will remain in the tissue for several days and prevent healing and SertaSil® from working. Preferably antiseptics should not be used. If absolutely necessary, briefly use 3% Hydrogen peroxide + as a light debrider as described in Section 4.

DO NOT let the wound become wet or moist.

Avoid the wound, the SertaSil® layer and the dressing getting wet or moist from the outside, e.g. from licking, rain or puddles, or from the inside, e.g. from sweating.

Should that occur, clean off the old SertaSil®, wash and dry the wound and apply a new layer of SertaSil® and secondary dressing – as described in sections 5, 6 and 7.

In case of excessive sweating, consider the option not to cover SertaSil® with a secondary dressing.

Store SertaSil® refrigerated

Keep SertaSil® away from direct heat sources

Avoid direct sunlight, radiators, window sills, pockets near to the body, hot cars etc.

Use within 15 days of first opening an SertaSil® bottle

Minimise bottle contamination

If a SertaSil® bottle has touched the wound, use alcohol or isopropyl alcohol to wipe it clean.

Occlusive dressings should be avoided

SertaSil® is intended for non-sterile wounds

Use only on sterile wounds after deemed appropriate by the treating veterinarian.

Container sizes

2 g and 10g.

www.SertaSil.com

Please visit www.SertaSil.com.