TenderWet® active:
Questions and Answers
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I. Product

1. Shelf life

**Question:**
Why can TenderWet active be kept for only three years and not five?

**Answer:**
The shelf life of the product means that, until the stated expiry date, its specified quality remains in effect. This has to be demonstrated with technical analyses once the product has been stored for a suitable period. And that means that for a shelf life of five years, analyses have to be carried out on five-year old products.

In order that, for new products, there should not be too long a wait before their introduction, the law provides for an exception. If a product is stored for 1.5 years at a raised temperature and passes the technical tests, a shelf life of three years may be given. This procedure has also been described for TenderWet active.

The shelf life of TenderWet active can be extended once suitable old products are available and they have passed the technical tests.

2. Ringer’s solution

**Question:**
What is the difference between Ringer’s solution and physiological saline solution?

**Answer:**
The two solutions are very similar; both contain salt (sodium chloride = NaCl). Ringer’s solution also contains potassium (K+) and calcium ions (Ca2+), both of which are of fundamental importance to the cells of the organism.

**Question:**
How is TenderWet active activated?

**Answer:**
TenderWet active is activated with Ringer’s solution, which is composed as follows:
- Sodium chloride (NaCl) 8.60 mg/ml
- Calcium chloride (CaCl2 x 2 H2O) 0.33 mg/ml
- Potassium chloride (KCl) 0.30 mg/ml
**Question:**
Why is TenderWet active activated with Ringer’s solution and not with physiological saline solution?

**Answer:**
Laboratory tests with human fibroblasts have shown that cells survive for a while in Ringer’s solution, but not in physiological saline solution. The initiators of the investigation go so far as to describe physiological saline solution as “too tissue-toxic”. (A. Kallenberger et. al.: “Experimentelle und bakteriologische Untersuchung zur Wahl des Spülmittels für antibakterielle Spüldrainagen”, Hierholzer and Rehn (Publisher): Die posttraumatische Osteomyelitis; 1970; Schattauer; New York).

These results are backed up by practical experience, which points to a slowing-down of wound healing on prolonged use of physiological saline solution. Unfortunately, however, these results have not been systematically documented.

The laboratory results, however, suggest that we are on the “safe side” with Ringer’s solution. For this reason, Ringer’s solution is used for the activation of TenderWet active.

Just how tissue-protecting Ringer’s solution is has been exemplified by the fact that it is used in the transport of organs for transplantation.

**Question:**
How can the different effects of Ringer’s solution and physiological saline solution be explained?

**Answer:**
Ringer’s solution contains in addition to salt also potassium and calcium ions. The balance of concentrations of all three ions (including sodium ions from the salt) plays a major role in the functioning of the cells. If a wound treatment is carried out over a long period, during which dressings soaked exclusively with physiological saline solution are used, this balance is continuously disrupted. The body tries to balance it out, but this costs energy. Patients with chronic wounds are usually older persons whose health is already compromised and it is entirely conceivable that such an ion imbalance would significantly disrupt or delay the healing process.

3. **Absorbing and rinsing effect**

**Question:**
What is the absorbing and rinsing effect?

**Answer:**
Although TenderWet active is already saturated with Ringer’s solution before application, it absorbs secretions including the proteins and cell debris they contain. The reason why this happens is that the Ringer’s solution is exchanged for the waste-laden secretions. The explanation for this process is that the molecules from the wound (e.g. proteins) are more strongly bound than the salts of the Ringer’s solution. A similar effect is exploited in chemistry to separate substances groups from each other (in chromatography).

The exchange described causes continuous rinsing of the wound, accounting for the high level of effectiveness of TenderWet active.
Has the absorbing and rinsing effect been proved?

As is often the case in science, the exchange reaction of the absorbing and rinsing effect is a model, which attempts to explain an observation from practice. But the model is also supported by laboratory investigations. It has been shown, for instance, that TenderWet active continuously releases Ringer’s solution. And it really is Ringer’s solution that is released, not just water. Measurements have also shown that TenderWet active absorbs protein that was fixed on gauze.

Question:
When absorbing proteins, can TenderWet active differentiate between “good” and “bad” molecules?

Answer:
Proteins are absorbed and bound in an unspecified manner. Enzymes essential to life are also taken up, but in practice this is not significant, since otherwise TenderWet active would not have so positive an effect on wound healing. The phenomenon is understandable when one knows that all enzymes have a very short lifespan, in some cases only one or more seconds. (If that were not the case, the physiological processes could not be controlled.) For this reason, TenderWet active probably absorbs almost only “used” proteins and so avoids further disrupting the biochemical processes.
Question:
Why does the absorbing and rinsing effect regulate the flow of secretion and thereby reduce the oedema formation?

Answer:
If a large quantity of secretion is formed which cannot drain away, the danger exists that an oedema (= fluid build-up in the tissues) may develop. Oedemas disrupt the supply of nutrients to the cells and therefore also the wound healing. Profuse secretion flow therefore needs to be controlled.

The secretion flow (if not caused by vascular damage) is the self-cleansing mechanism of the body, by which a wound is cleansed. One of the causes has been removed, secretion formation is reduced.

TenderWet active regulates secretion flow, on the one hand, by rapid wound cleansing - i.e. the cause is remedied. On the other hand, it avoids the production of secretions being stimulated by strong suction. Unlike dry hydro-active wound dressings, TenderWet active does not develop a strong absorption effect.

4. Absorption capacity

Question:
Is the absorption capacity of TenderWet active different from that of TenderWet?

Answer:
The absorption capacity of TenderWet active has been optimised with a specially developed process (known as Power Activation Technology, or P.A.T. for short). Thus TenderWet active contains on average about 20% more Ringer’s solution than the standard version. Taking the 7.5 x 7.5 cm size as an example:

<table>
<thead>
<tr>
<th>Activating volume of TenderWet&lt;sub&gt;r&lt;/sub&gt; 7.5 x 7.5 cm</th>
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</thead>
<tbody>
<tr>
<td>Activating volume [ml/cm²]</td>
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<tr>
<td>TW normal</td>
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<tr>
<td>TW duo</td>
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<tr>
<td>TW active</td>
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</table>

Question:
What does the term “Power Activation Technology” (P.A.T.) stand for?

Answer:
TenderWet active is activated using a specially developed and validated process, known as Power Activation Technology, or P.A.T. for short. Simplifying, this process can be described as follows:

Firstly, the optimum volume of Ringer’s solution is dosed to the individual wound dressing pads. Then the absorbing and rinsing core is “power activated” with a specifically developed heat treatment.
This causes TenderWet active to absorb the optimum quantity of Ringer’s solution, so that the effective absorption capacity of the wound dressing pad is significantly increased, whilst the high retention capacity is retained. At the same time, the absorbing and rinsing core, and therefore the entire wound dressing pad, is made softer and more flexible.

Using P.A.T., it has been possible to increase the absorption capacity whilst maintaining a high retention capacity and thus further to improve the efficiency of TenderWet active. At the same time, the wound dressing pad is simpler to drape, so that contact with the wound base is assured and pain on dressing application is more readily avoided.

**Question:**
What does it mean if Ringer’s solution remains behind in the peel-off bag?

**Answer:**
In order to ensure that TenderWet active is always optimally activated, a small excess of Ringer’s solution is used. Due to slight variations in absorption capacity from one wound dressing pad to the next, the excess of Ringer’s solution is sometimes more, sometimes less.

**Question:**
What advantage comes from the increased quantity of stored Ringer’s solution?

**Answer:**
The increased volume of Ringer’s solution has the effect that wounds with a larger fluid requirement can also be treated optimally. Drying out or adhesion of the wound dressing pad will occur less often. However, since the moisture requirement of wounds can be very high in exceptional cases, it cannot be guaranteed that sufficient Ringer’s solution will always be available. These, however, are rare exceptions.

**Delivery of fluid from TenderWet® (7.5 x 7.5 cm)**

<table>
<thead>
<tr>
<th>Delivery of fluid (g/24h)</th>
<th>TW with 30ml</th>
<th>TW with 35ml</th>
<th>TW with 40 ml</th>
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<td></td>
<td>6.8</td>
<td>7.2</td>
<td>7.6</td>
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</table>

**Question:**
Does the increased quantity of stored Ringer’s solution prevent TenderWet from adhering to the wound?

**Answer:**
The causes of adhesion with the wound are manifold. Apart from drying out of the wound dressing pad, fibrin coatings, setting of the secretion, bleeding, etc., all also play a part. Adhesion arising through drying out of the dressing will now occur less often. The other causes also arise only rarely, so that adhesion becomes very unlikely, though not impossible.
II. Application

1. Dressing changes

Question:
Does TenderWet active also have to be changed daily?

Answer:
TenderWet active stores more Ringer’s solution and therefore remains moist for longer. Since the moisture requirement of each wound can vary greatly, it is not possible to predict how long the wound dressing pad remains moist enough. For this reason, even TenderWet active should be changed daily.

Question:
Isn’t a daily dressing change too expensive? Other wound dressings can remain on the wound for several days.

Answer:
Daily dressing change is only too expensive if it is not necessary. TenderWet active is used for the treatment of infected wounds and wounds in the early cleansing stage. Wounds of these types must be inspected daily so that any worsening, such as the spread of an infection, can be recognised in good time. Given this indication, daily dressing change is necessary in any case, regardless of which wound dressing is used. Against this background, it is clear that it is those wound dressings that are only economical with long dressing change intervals which are too expensive for these indications, and not TenderWet active.

Question:
Does TenderWet active treatment have to be avoided if daily dressing changes cannot be realised by the physician or out-patient care staff?

Answer:
In numerous cases, it has been found that patients or their relatives can perform TenderWet dressing changes themselves without difficulty. With TenderWet active, this becomes even easier, since activation does not have to be carried out. That this is not merely an emergency solution is confirmed by many physicians and nurses. The patient himself is involved, which takes him out of the passive “victim role”. This positively influences both the patient and the healing process. The healing of chronic wounds is very strongly influenced by such psychological factors.

This route is not always possible, and in such cases, the use of PermaFoam (comfort) should be recommended.
2. Contact with the wound base

Question:
Why must contact with the wound base be ensured?

Answer:
Every wound dressing, not only TenderWet active, can only effectively absorb wound secretions if it is in close contact with it. If the secretion is to be completely removed from the wound, the dressing must contact the wound base. If this is not the case, secretions remain on the wound surface.

Question:
Can contact with the wound base be assured with TenderWet active?

Answer:
TenderWet active is very soft, smooth and conformable, so that it readily adapts to the wound. For this reason, contact with the wound base can usually be guaranteed with TenderWet active.

Question:
In what cases can contact by TenderWet active with the wound base not be guaranteed?

Answer:
If TenderWet active is too large, to fill small wound pockets or indentations. If the smallest TenderWet active is too large, then Sorbalgon should be used.

Question:
What happens if secretion remains in the wound?

Answer:
Secretion residues, which are also apparent as "pockets of moisture", are an excellent nutrient medium for bacteria. The danger therefore exists that infections could spread from here. To avoid this danger, no secretion resides should remain on the wound.
3. Pressure on the wound

Question:
How does pressure affect wound healing?

Answer:
As in most cases, it is a matter of degree. Slight pressure has a positive effect on healing, whereas a too great force can even itself cause wounds (e.g. in diabetic foot lesions).

Question:
Does TenderWet active exert a too great pressure on the wound, due to its relatively high weight compared to other dressings?

Answer:
The pressure that TenderWet active exerts on the wound is irrelevant compared to the pressure arising from the fixation. This applies to all dressings currently on the market. It should be noted that other wound dressings become increasingly heavier due to absorption of secretions, whereas TenderWet active approximately maintains its weight (due to the exchange reaction).

It should be noted that pressure is always dependent upon the area; the greater the area, the smaller the pressure. For this reason, a TenderWet active of approximately 7.5 x 20 cm size does not exert any greater pressure, despite its greater weight, than a 4 cm wound dressing pad!

4. Compression treatment

Question:
Is TenderWet active also effective under compression bandaging; or is the fluid all squeezed out?

Answer:
TenderWet active retains almost all its storage capacity under compression bandaging. It has been shown by laboratory investigations that, under pressure (35 mm Hg), TenderWet active even has greater retention than PermaFoam. These findings have been supported by the first clinical observations, which confirm the suitability of TenderWet active for use under compression bandaging.

Question:
How should TenderWet active be fixed under compression bandaging?

Answer:
Ulcus cruris patients have, on account of their condition, a very badly affected and sensitive skin. For this reason, all adhering fixing materials should be avoided as far as possible. No matter how good these products may be, they represent an additional load, which should be avoided. Against this background, conforming bandages should be used. Peha-haft has proved particularly valuable here, since a bandage of this type creates hardly any additional bulk.
Question:
Should TenderWet active be additionally padded before application?

Answer:
Padding is not necessary, since TenderWet active is very soft and adapts to the body without difficulty.

5. Maceration

Question:
What is maceration?

Answer:
Since the term maceration is not consistently used, misunderstandings often arise. In general, maceration of the skin is taken to mean that it is softened and lastingly damaged. The lasting damage is caused by the killing of living skin cells. According to this definition, softening of the (dead) epidermal skin layer or the temporary changing of the living skin cells (e.g. skin appearance after a bath) should not be regarded as maceration. It should be pointed out, however, that there is no consensus in specialist circles about this. Before discussing this topic, clarity should be achieved about the term to avoid misunderstandings.

Question:
Does TenderWet active cause maceration of the wound margins?

Answer:
TenderWet active does not attack living cells, so that no damage to or maceration (see above) of the skin occurs. However, conditions can occur which are interpreted as maceration:

- The skin is constantly renewed and old (dead) skin cells are shed. These skin scales are normally small and are not usually apparent. With TenderWet active, it can occur that, due to the moisture on the skin, these skin scales remain and form a whitish film. This has no negative influence on wound healing. It can also easily be removed with a moist dressing.

- The skin at the wound margins must be looked after in order to avoid damage. This applies to a particular extent for older patients and chronic wounds. If it is neglected, particular when combined with moist, hydroactive wound dressings, skin reactions such as reddening can arise. What takes place here is not maceration in the true sense (see above). If it does arise, the wound margins should be treated with a greasy cream containing neither preservatives nor perfume (to which the affected skin may react). Alternatively, TenderWet active may also be used in combination with Atrauman, so that the wound margins are protected by the ointment dressing.

- If the absorption capacity of a wound dressing is exceeded, the wound secretion is no longer completely absorbed. This may lead to the secretion wetting the skin of the wound margins. Since the secretion is in general very aggressive, on long contact, maceration (see above) may result.
6. Wetness and the cooling effect

Question:
How is it possible to prevent the Ringer’s solution running out of the wound dressing pad?

Answer:
Thanks to the newly developed activation procedure, the Ringer’s solution is firmly bound by TenderWet active. If excess solution is removed from the wound dressing pad by light pressure before application, the danger of “leakage” is greatly reduced.

Question:
Does TenderWet active cool the wound too excessively?

Answer:
No, because the cooling effect of evaporation plays only a minor part in the use of TenderWet active, since evaporation is greatly restricted by the protective foil and by the fixation.

As a rule, wound dressing pads should not be used cold (e.g. from a cold car in winter), but hand warm. The wound dressings can be warmed up before use in the peel-off bag (e.g. between the hands or on a moderately warm radiator).

7. Germ reduction in wounds

Question:
How can bacteria be removed effectively from wounds?

Answer:
The most effective method is surgical debridement. This clears necrotic tissue and other dead material from the wound and thereby also the bacteria that have colonised this dead material. At the same time, however, the basis for the life of the bacteria is removed, since bacteria are able to multiply well in dead tissue without being effectively combated by the immune system.

Surgical debridement may be enhanced or replaced by wound rinsing if this is medically desirable.

Question:
Is there any need, after surgical debridement (see above), to treat the cleansed wound with TenderWet active?

Answer:
Treatment with TenderWet active is recommended even after surgical debridement. In general, debridement is not sufficient to cleanse a wound completely, so for that reason subsequent wound rinsing (see above) with TenderWet active is worthwhile. TenderWet treatment also accelerates wound cleansing and simplifies debridement.
**Question:**
Can TenderWet take the place of debridement?

**Answer:**
TenderWet active does not cleanse wounds so rapidly and effectively as surgical debridement. TenderWet treatment, on the other hand, is gentler, since only dead tissue is removed, and no living tissue. Whereas in surgical debridement the risk remains that healthy tissue will also be excised. Particularly in the case of chronic wounds, this is not desirable.

It needs also to be considered that surgical debridement requires special education and adequate experience. By contrast, TenderWet active can be used by anyone and without any specialist knowledge. It is this argument that makes the use of TenderWet active very popular with all non-surgeons.

**Question:**
How does the effect of TenderWet active differ from antimicrobial silver dressings?

**Answer:**
Silver dressings release silver ions, which kill bacteria at a greater or lesser distance from the dressing. It should be noted that dead bacteria (through endotoxins) can also negatively influence wound healing.

Evidence for the effectiveness of the silver dressing is offered by laboratory tests whereby, generally, nutrient-free suspensions are used, in which bacteria cannot grow. This makes the effectiveness of the dressing in practice appear questionable.

Preliminary investigations have shown that bacteria also tend to form “biofilms” in wounds, which provide a kind of protective layer in which the bacteria can multiply relatively unhindered by external influences. It has also been shown that silver-impregnated wound dressings cannot effectively combat bacteria in biofilms. Necrotic tissue and coatings can have a similar protective effect for bacteria, which would severely limit the effectiveness of silver dressings.

Not only does TenderWet active absorb bacteria with the secretion, thus reducing germ load, it also removes the basis for the life of the bacteria (see above). Dead tissue is effectively removed, so that germ multiplication is severely restricted. It is clear from this that TenderWet active removes the cause of infection, namely the basis for the life of the bacteria. Furthermore, bacteria (both alive and dead) are removed from the wound, so that endotoxins cannot unfold their effectiveness.

Summarising, it can be seen that TenderWet active and silver dressings function according to entirely different principles, making a direct comparison impossible. However, effective wound cleansing is required in every case. The killing of bacteria is meaningful as an additional measure, although it is insufficient as a sole treatment. This means that TenderWet active is always needed, whilst “silver” is only sometimes required in addition.
Question:
How securely does TenderWet active bind bacteria and can re-infection of the wound occur?

Answer:
No wound dressings, not even the silver dressings, are able to bring a wound into a sterile condition. All suitable treatments provide for germ reduction, but a relatively large number of bacteria always remain in the wound. For this reason, it is entirely irrelevant whether 100% of bacteria are bound up by a dressing. However, it is important to ensure that bacteria are removed from the wound and firmly bound by the wound dressing. Against this background, a series of tests was carried out using TenderWet with this in mind. The results were summarised in an article to be published in a specialist journal. The most important facts from this are:

- Electronmicrographs show that bacteria absorbed by TenderWet are bound to the super absorber.
- TenderWet effectively absorbs germs from an agar plate and binds them in its interior.
- TenderWet prevents the growth of germs in a nutrient solution. An example of this is the result for Staphylococcus aureus:

Staphylococcus aureus

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<th></th>
<th>control (0h)</th>
<th>control (24h)</th>
<th>control with Ringer (24h)</th>
<th>TenderWet® (24h)</th>
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</table>
8. Pain

Question:
What types of pain can occur during wound treatment with TenderWet active?

Answer:
The absence of pain, particularly with chronic wounds, indicates that the normal physiological processes have been disrupted. The nerve endings may have been restricted in their function by necrosis and toxins. If the wound has been cleansed by surgical debridement or by TenderWet, functional capabilities are restored and pain may occur. This, however, is a good sign, showing that the healing process has resumed. If the pain is perceived by the patient to be intolerable, a suitable pain-killing treatment should be instigated at an early stage.

It has been found that the additional use of Atrauman (between wound and TenderWet active) has a pain-reducing effect. The reason for this is unclear and it does not always work, but it is worth a try.

When assessing pain, it should be noted that the subjective perception of pain varies greatly. Whilst one patient is pleased to be able to “feel it healing”, another may not be able to endure the pain. It is clear, therefore, that pain may be brought about only partly by a wound dressing.

Three “special forms” of pain will now be mentioned:

- Pain can arise during a dressing change if the wound and its site are very sensitive. This pain may be lessened in some cases by moistening the wound with Ringer’s solution before applying a new dressing and by using a wound dressing pad that has been warmed in advance.

- In rare cases, some wounds “use up” a large amount of Ringer’s solution. This can lead to the wound dressing pad drying out prematurely. Some patients then feel a slight “pulling” pain, which ceases if the dressing is moistened again. With the introduction of TenderWet active, however, this type of pain will become still less common.

- A high concentration of potassium ions can trigger pain. In the first TenderWet generation (until 1998), a super absorber was used which released potassium ions. Even though relevant observations have never been made, it cannot be ruled out that the occurrence of pain was negatively influenced by the old TenderWet generation. This possibility is now definitely a thing of the past, but if a user may have had a negative experience years ago, it is worthwhile making a new test with TenderWet active.