# Alpha SmartTemp Liners Frequently-Asked Questions

# 1. How is this liner different from other liners, regardless of silicone, urethane or thermoplastic elastomer?

The Alpha SmartTemp Liner uses Outlast<sup>®</sup> technology to pull heat away from an amputee's limb throughout the day as well as during times of high-activity or elevated temperature. To help illustrate this, think of a sponge. When dry, a sponge is firm to the touch. When placed in water, a sponge soaks up the water until is it completely saturated. Once all the water is absorbed by the sponge, over a period of time the water evaporates out of the sponge and it returns to its dry state. The Alpha SmartTemp Liner with Outlast<sup>®</sup> goes through the same basic cycle, but with <u>heat</u> rather than the water in our sponge example. The length of time it takes for all the absorbed heat to be released can vary depending on a person's environment and if the liner is left on a residual limb or removed.

The Alpha SmartTemp Liner also differs from other liners in regards to its firmness. Using the same sponge example as above, the dry sponge is firm to the touch. As the sponge absorbs water, it becomes softer to the touch and more flexible. After the water is removed from the sponge and it dries, the sponge returns to its firm state. The Alpha SmartTemp Liner with Outlast<sup>®</sup> responds similarly to <u>heat</u> as it is absorbed and stored in the liner. The silicone of the liner is firm before it is donned onto a residual limb. As the liner absorbs heat, the silicone properties begin to act more like thermoplastic elastomer. When the liner is removed from a limb or an amputee moves to a cooler environment, the stored heat is released and the silicone reverts back to its normal state.

At any activity level, the Alpha SmartTemp Liner absorbs heat while on an amputee's limb creating a comfortable skin temperature level by balancing the amputee's skin temperature and the liner temperature. The liner though can become saturated with heat and can reach a point at which it can no longer absorb more heat. Once the liner is saturated with heat it needs to be cooled back to room temperature and return to its normal state. After the liner is cooled, which could be achieved by doffing the liner and letting it rest or by going into a cooler environment such as an air-conditioned building, it will once again be ready to absorb and store heat.

#### 2. How does this liner work in cold temperatures?

The Alpha SmartTemp Liner with Outlast<sup>®</sup> works the same in warm or cold temperatures. The liner will absorb heat from the residual limb to create a comfortable skin temperature. However, the colder the environmental temperature, the quicker the liner dissipates the absorbed heat.

### 3. How does this liner stop a patient from sweating?

The technology in the Alpha SmartTemp Liner does not stop sweating. The Outlast<sup>®</sup> material that is included in the liner will delay the onset of sweating and should delay patients from excessively sweating. During clinical testing, several amputees reported they could wear the liner 14 to 20 hours without having to remove the Alpha SmartTemp Liner, pour out the accumulated sweat, dry their limbs and liners, then re-don the liners. By incorporating Outlast<sup>®</sup> with the silicone, the liner absorbs heat from a person's limb and environment, stores it in the liner, and delays sweat from starting.

Every amputee is different. A person's activity level, environment, and personal metabolism are all variables that contribute to how long the onset of sweat is delayed. This can vary for each individual yet all amputees who wear the liners will realize the benefits of the liner technology.

# 4. This is a silicone liner but the details say it acts like a thermoplastic elastomer. What's the liner durometer, or firmness, like?

The Alpha SmartTemp Liner is a silicone and has a durometer similar to our Alpha Silicone Liners. By incorporating Outlast<sup>®</sup> with the silicone, the liner absorbs heat from a person's limb and environment and stores it in the liner. Once the Alpha SmartTemp Liner is donned, has absorbed heat, and is warm, the liner durometer then is similar to that of thermoplastic elastomer, or gel liner. The liner actually becomes more comfortable throughout the day as it is worn.

## 5. Who is this liner appropriate for...or for what activity level?

The liner is suitable for any activity level. Amputees who regularly experience mild/moderate perspiration or discomfort from heat or sweat are candidates for the Alpha SmartTemp Liner. Additionally, amputees who currently wear silicone and like its durability yet desire a more comfortable interface are also be appropriate candidates for this liner.

However, amputees with fragile or highly-sensitive skin may not be best suited for Alpha SmartTemp Liner.

# 6. Does the Alpha SmartTemp Liner retrofit with other liners?

Yes! Any liner with WillowWood's progressive or symmetrical AK profiles will retrofit with the Alpha SmartTemp Liner. Alpha Classic Liners, Alpha Hybrid Liners, and Alpha Silicone Liners with progressive profiles will retrofit with an Alpha SmartTemp Liner with a progressive profile. Likewise, an Alpha Classic AK Liner, Alpha Hybrid AK Liner, or Alpha Silicone AK Liner with a symmetrical AK profile will retrofit with the Alpha SmartTemp AK Liner.

## 7. Do these liners need to be stored differently?

No, Alpha SmartTemp Liners may be stored the same as other Alpha Liners.

#### 8. What are the care instructions for the silicone of the Express Liner?

The care instructions for this liner have not changed. At the end of each day, wash the liner with water and a body soap that does not irritate the skin. Allow the liner to dry on the drying stand overnight. Once a week, disinfect the liner by wiping the interior with ethyl or isopropyl alcohol and allowing the liner to dry overnight.

### 9. Will the performance of the Outlast<sup>®</sup> material reduce over time? No, Outlast<sup>®</sup> does not degrade over time.

#### 10. Is this liner suitable for use with amputees who are also diabetic?

The Alpha SmartTemp Liner is suitable for a variety of patients. Several of our test patients who participated in clinically testing this liner were diabetics. These patients had healthy residual limbs and experienced no problems with the Alpha SmartTemp Liner. The decision to use this liner on diabetic amputees is up to an individual's clinician. An amputee's lifestyle/activity level, environment, and metabolism as well as skin sensitivity should be considered in clinical decision-making.

# 11. How does the Alpha SmartTemp Liner compare to the Alpha Silicone or WillowWood Express Liners?

All of these liners use a proprietary, platinum-cured, medical grade silicone. The liners do share some common traits such as profiles and fabrics yet they also each have unique characteristics. <u>WillowWood Express Liner</u> is a softer-durometer silicone that replicates the feel and comfort of thermoplastic elastomer (gel) liners. The profiles of this liner are uniform for transtibial use and AK for transfemoral use. Original or Select fabrics are used for transtibial liners and Spirit or MAX fabrics are used for transfemoral liners.

<u>Alpha Silicone Liner</u> is unique blend of silicone, Vitamin E, and skin conditioners with a surface that is non-greasy and comfortable against the skin. The profiles for this liner are progressive for transtibial use and Symmetrical AK for transfemoral use. The Alpha Silicone Liner uses the one-way stretch Select fabric to control pistoning.

<u>Alpha SmartTemp Liner featuring Outlast</u><sup>®</sup> is the only liner in the WillowWood product line, as well as within the industry, that blends silicone with Outlast<sup>®</sup>, the original heat management technology. The liner absorbs heat from the residual limb, stores it, then releases the heat as the liner cools, thereby delaying the onset of sweat and helping an amputee stay comfortable throughout the day. The profiles for the Alpha SmartTemp Liner are progressive for transtibial use and Symmetrical AK for transfemoral use and can retrofit with any Alpha Liner having these same profiles. The liner uses Select fabric.

# FAQs for Customer Care use only

#### 12. How long has the liner been in testing?

We've been developing and testing this liner, both mechanically and clinically, for over a year. Outlast<sup>®</sup> Technology has been thoroughly tested for over 20 years.

#### 13. How many amputees have worn and tested this liner?

We have clinically tested these liners internally as well as externally through beta sites. Internally, we worked with over 50 patients, including both transtibial and transfemoral amputees, for clinical testing.

#### 14. Will casting liners be available?

Yes, although Alpha Silicone casting liners in the same profile may also be used when casting a patient.

#### 15. Why is this liner not recommended for patients with sensitive/fragile skin?

The firmness of this silicone liner may be too firm for amputees with highly sensitive or fragile skin.

#### 16. Why is the inside of this liner blue?

The blue interior of the Alpha SmartTemp Liner is only to help differentiate this new liner from others within WillowWood's product line.

#### 17. The inside of the liner is blue. Will that come off on a patient's skin?

We have completed clinical testing as well as biocompatibility testing of the silicone formula and the blue will not 'stain' or 'transfer' onto a patient's skin.

#### 18. The blue looks like latex. Is latex included in this liner?

No latex is in the Alpha SmartTemp Liner.