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WITH CLINICAL INSIGHT FOR EVERYDAY PRACTICE

Choosing the Best Liner

To determine the best fit, prosthetists should consider several factors, including the age, allergies and activity levels of their patients.

By Dan Pastorius

Whether one is riding a bike, picking up groceries or dancing a jig, comfort, control and confidence are important requirements in the everyday lives of lower-limb amputees. Designed to facilitate these particular activities are liners — roll-on sheaths composed of various materials that are used to control swelling, skin abrasions and habitual pain amputees are likely to experience. Created using a soft, flexible substance and rolled over one's residual limb for protection and the suspension of their prosthetic device, liners give amputees the flexibility they need to participate in even the smallest of tasks.

As O&P manufacturers continue to offer a variety of liners with different benefits and applications, it is important to determine what liner works best with a person's particular lifestyle. Proper fit and adequate manipulation are significant deciding factors, as well as age, allergies and activity level. Liners are available in many sizes, thicknesses and materials. These variables make it crucial that amputees and prosthetists are knowledgeable about the liner options are available to them, as well as the latest developments in forward-looking technology.

In this overview of liner options, *O&P Business News* provides information from several liner manufacturers. Although the participating companies comprise a small sample of the many manufacturers in the industry, the information provides a general idea about different types of products available for O&P practitioners. Each liner presented here provides the necessary elements to help maintain adequate fit and preserve the general skin and health of the residual limb. Because of the multitude of companies, products and alternatives available, when choosing what liner works best for practitioner and patient, one can never be too prepared.

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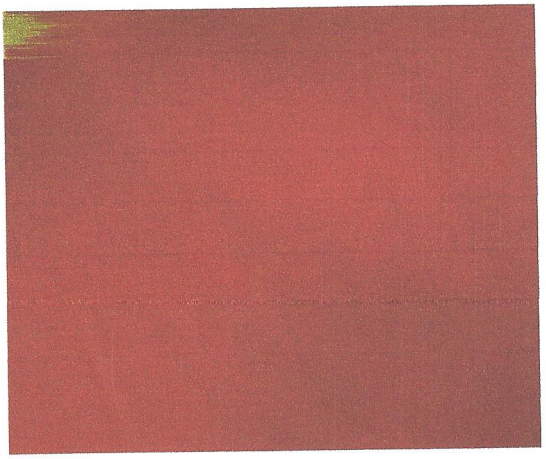


Ohio Willow Wood

With a mission of providing the O&P community worldwide with products that "free the body… free the spirit®," Ohio Willow Wood offers lower limb amputees comfort and patient satisfaction with its Alpha® family of liners. Noting that each of the company's liners are offered in cushion and locking styles as well as a variety of fabric colors, Lisa Watkins, communications coordinator for Ohio Willow Wood, described several options available for prothetists and patients:

- Alpha Original Liners — Alpha Original Liners offer a limb and skin protection interface that surrounds the residual limb in a layer of skin-friendly, mineral oil-based thermoplastic gel.

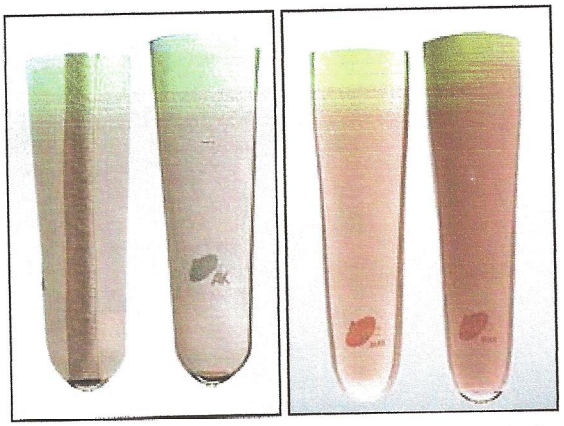
- Alpha Spirit Liners — The Alpha Spirit Liners offer the same skin-friendly, mineral oil-based gel as the Alpha Original Liners, but feature a more flexible, yet supportive, fabric. Amputees with limited hand dexterity may be better served by this more flexible fabric.

- Alpha MAX Liners — Featuring Ohio Willow Wood's Stabilizing Strip, the Alpha MAX Liner fabric deters movement and gel delamination. These features work together to allow a lengthy circumferential stretch, while simultaneously reducing any longitudinal movement.

- Alpha AK Liners — Designed for transfemoral amputees with a specific AK gel pattern, the Alpha AK Liner offers the same skin-friendly, mineral oil-based gel as the Alpha Original Liners, and uses the Alpha Spirit fabric. Locking AK Liners feature a Stability Strip to help prevent pistoning of the residual limb in the socket.

- Alpha P-POD™ Liners — The Alpha P-POD Liner is designed specifically for young amputees. Featuring the Alpha gel, the liners cushion the limb and provide protection from sheer impact and abrasive forces. The liners feature MAX fabric, which is durable enough to meet the needs of active, young amputees.

- Alpha DESIGN Liners currently for transtibial and Symes amputees — Designed for amputees with less than optimally shaped residual limbs, when prefabricated liners will not work and comfort is critical. DESIGN Liners offer the same skin-friendly, mineral oil-based gel as other Alpha Liners. Practitioners decide the gel pattern within the custom liners to provide amputees maximum comfort.



Ohio Williow Wood offers lower limb amputees its Alpha® family of liners. The Alpha AK Liner (left) is designed for transfemoral amputees with a specific AK gel pattern. The Alpha MAX Liner (right) fabric deters movement and gel delamination.

Remarking that the composition of Alpha Liners has been proven in independent laboratory tests to be free of allergic reactions, Watkins described how the liners provide the residual limb with protection from abrasions and outside forces while simultaneously conditioning and improving the skin.

"The most unique aspect of Alpha Liners, regardless of particular style, is the mineral oil-based gel," she said. "When compared to silicone or urethane used in other liners, the thermoplastic elastomer gel is significantly more skin friendly and is physically more comfortable to the amputee. Combine the proprietary Alpha gel with

the durable fabrics developed specifically for Alpha Liners, and practitioners are able to provide long-lasting comfort for their patients."

Watkins explained that all Alpha Liners are covered in durable fabrics made specifically for Ohio Willow Wood that extend the life of the liner and make donning and doffing easy for amputees. The Alpha Spirit fabric can be used with Velcro®-type material, which can be helpful when using suspension sleeves for added suspension and security. Practitioners can choose from a variety of gel thicknesses to maximize amputee comfort and socket fit, and the liners are available for all age groups, from infants to the elderly.

Euro International Inc.

Upon application, the Euro International's Context Gel Liner (left) adapts to the residual limb and offers skin caring properties, decreases impact, proves optimal for stump embedding and can be customized to its user. The company offers 22 other liner types, including three styles designed exclusively with additives to assist in skin care.

In developing a detailed criteria checklist that helps prosthetists choose the best liner for each patient, Euro International aims to make sure every amputee has the proper liner based on his or her activity level and rehabilitation goals. Company officials said that its large selection of liner choices both in cushion and locking is what makes it easy for O&P workshops and military hospitals to use its products.

"Our sales team and myself make every effort to assist our customers with the best possible liner selections for their patients," said Richard L. Hughes, CPO, technical director for Euro International. "Our liners are manufactured in seven types of silicones or gel. The key to our success with our liners is the outer fabric that has been chosen to specifically meet the patients' needs. Finding the best fabric choice for each type of silicone or gel is what allows the patient to easily roll their liners on. Our newest advance in technology is our Contex Gel liner, which proves exceptionally easy for geriatric patients to put on."

Upon application, the Contex Gel liner adapts to the residual limb and offers skin caring properties, decreases impact, proves optimal for stump embedding and can be customized to its user. In addition, Euro International offers 22 other liner types, including three styles designed exclusively with additives to assist in skin care. Aloe vera is used in the company's Skin Care and Skin Care Plus liners to offer a cooling and soothing effect for those with sensitive skin conditions. A combination of menthol and aloe vera are used in the Active Care liners, providing a mild topical anesthetic and promoting healing.

Hughes explained that the company uses different types of materials to accommodate varying activity levels and stabilities, maximizing patient fit and comfort.

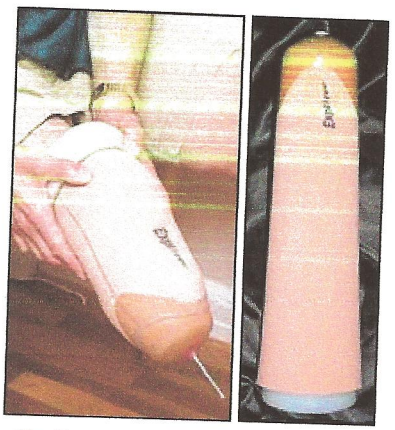
"Whether you prefer silicone or gel, we have a liner that will work well with you," Hughes said. "A positive attribute of our Contex Gel liner is its ability to be secondarily formed over a patient model, allowing the practitioner to fit complex limb shapes. This liner is an ideal choice for patients who experience fluctuation in volume or have larger residual limbs."

Euro International's silicone liners are available in sizes ranging from 12 cm to 45 cm, while its Contex Gel liners are available from 16 cm to 73 cm. Furthermore, the company features a liner range that allows practitioners to replace or upgrade to liners of a similar profile without having to rebuild the socket. Future plans include the launch of its Contex Gel with Eternal Matrix, AK Control with External Matrix and Post-Operative Compression liner, designed to help shape the residual limb by combining complete circumferential pressure with well fitting, ridged dressing shapes.

Silipos Inc.

Working behind the slogan "Tomorrow's Technology for Today's Medical Challenges," Silipos provides cutting-edge liners designed specifically for low- to moderate-activity users. Dubbed Explorer® by company officials,

Silipos' liners contain a proprietary mineral oil gel that matches specific gel characteristics with the liners' specific function. The company's external fabric stretches more than 100% in all directions, and accommodates a variety of shapes and contours, providing unrestricted knee flexion. The inside and outside of the liners are treated with an antimicrobial agent, and are formulated to fit even the most difficult of distal shapes with uniform pressure.



The Explorer from Silipos is offered in both cushion liner and pin liner systems, with regular and reinforced suspension sleeves also available. The pin liner features a stabilizing matrix that reduces distal elongation and provides 360° control.

The Explorer is offered in both cushion liner and pin liner systems, with regular and reinforced suspension sleeves also available. The pin liner features a stabilizing matrix that reduces distal elongation and provides 360° control. Each of these liners can be cut to size with a regular pair of scissors without unraveling. The suspension sleeves and the liners do not require lotion or alcohol when donning or doffing. When explaining the Explorer's flexibility and ability to maintain shape, Marty Vogel, CPO, head of educational and technical services for Silipos, shared the evolutional process of the liner, from inception to its first use.

"The liner starts its life as a tube or trapezoidal shape," Vogel said. "It is easy to roll on to the limb and begins to take the shape of the limb quickly, with no heat required. Within days of continuous wear, the liner will look like the limb when removed. Both the gel and fabric accommodate to most shapes, and are comfortable from the first fitting."

Vogel said the inside and outside of the liners are treated with antimicrobial and antifungal properties that resolve problems such as socket odors and follicular infections. These properties clear up skin problems that have been caused by silicone, urethane and sticky TPE materials, in addition to allergies, burns, scars and other associated adhesions.

"There are no other oils or vitamins in these formulations to minimize the possibility of allergic or other skin reactions that often occur in the occlusive environment of our prosthetic liners and sheaths," Vogel explained. "We have independent tests showing the lack of skin direction performed by a third-party dermatologist. The durometer and physical characteristics have been chosen to easily fit to any bone prominences while providing a comfortable, protective cushion with uniform pressure."

There are three basic sizes to the Explorer line — medium, large and extra large. The medium and large sizes have plus-sized models that fit patients with larger proximal thigh proportions. Available in thicknesses of 3 mm, 6 mm and 9 mm, these models provide varying degrees of shock and shear absorption based on the patient's requirements. Traditional uniform shapes work well with most patients, and the company's tapered design provides additional distal cushioning and protection for mature and sensitive limbs.

Freedom Innovations

Initially developed by Stan Patterson, CP, a practitioner whose goal was to improve the lives of amputees demanding consistent high-level performance from their prosthesis, Freedom Innovations' Evolution SP Liner™ provides users with a soft, compliant and comfortable product that is highly tear resistant and does not compress over time. Company officials said that in keeping with the company's motto as an advanced technology prosthetics company, the Evolution liner is a combination of progressive technologies and unique materials, resulting in high-performance, custom-made devices.

The Evolution SP Liner from Freedom Innovations can be shaped to fit any sized residual limb. The platinum-cured exterior prevents bacteria from growing, controlling and minimizing odor.

Made of a biocompatible material that prevents adverse reactions from the body's tissues, the Evolution SP Liner can be custom shaped internally to support invaginated scars and externally to provide additional padding over bony prominences. Kurt Collier, CP, director of new business development and clinical services for Freedom Innovations, said that what sets this liner apart from the rest is that it is the only custom-made pin and cushion liner available consisting of platinum-cured silicone. This substance enables each liner to provide its user with custom comfort and unyielding support.

"The platinum formulation completely cures in 24 hours, assuring that the liner will not experience cold flow — which means that the liner is not going to change shape, thin out or crack over time," said Collier. "This allows the prosthetist the ability when assessing the fit of the prosthesis to focus his or her attention on the potential dynamics variable of only the limb and hard socket design."

In addition to providing ease of use when fitting, the Evolution SP is compatible with other devices while maintaining the user's comfort and high-performance expectations. The durability of the platinum-cured silicone enables practitioners to incorporate this interface into the amputee's preferred socket design. It can be used in conjunction with total surface bearing sockets, petalla tendon bearing sockets and supracondylar sockets, among other applications.

"The custom, shape-specific design provides amputees uniform pressures to the residual limb," he said. "This facilitates the fabrication of the hard socket interface by assuring the clinician that the starting point in the fabrication of the socket is reflective of the shape of the residual limb underneath the liner. Additionally, the durometer of the liner is such that it is going to assure that the residual limb under weight-bearing phases of gait is not going to migrate through the gel, which oftentimes leads to complications of the skin in certain areas of the residual limb."

The Evolution SP Liner can be shaped to fit any sized residual limb. The platinum-cured exterior prevents bacteria from growing, controlling and minimizing odor. Past fittings have included various transtibial and transfemoral amputees, Symes patients, patients with knee and hip disarticulations, and hemipelvectomy and transradial patients of all ages and activity levels.

ALPS

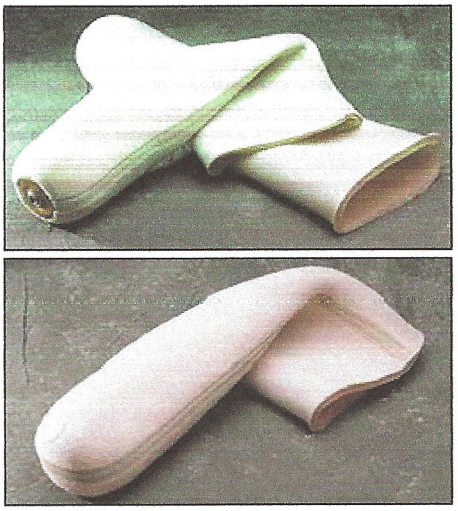
Offering performance, durability, ease of stretch, a soft durometer and various surface characteristics, the ALPS roster of liners cover a wide range of necessary applications. According to Kevin McLoone, manager of market development for ALPS, the company's wide variety of liners is able to fit most amputees' product needs comfortably and efficiently, while providing the best fit and stabilizing support available. Liners the company offers include:

- Easyliner Super Stretch™ — Combining softness, strength and elasticity because of ALPS' patented EasyGel™

formula, the Easyliner Super Stretch offers durability, comfort and a low coefficient of friction. The liner allows complete freedom of movement while simultaneously achieving superior total contact with the skin without restricting blood flow.

- Easyliner Fabric Reinforced ELFR™ — Captures the same capabilities of the Super Stretch, but features an elastic fabric cover that enhances stability and promotes easy donning and doffing. Provides excellent redistribution of forces serving to soothe skin and provides longer lengths to accommodate more users.

- Thermoliner Cushion Liner™ — The Thermoliner Cushion Liner allows prosthetists to customize and shape a gel interface to the configuration of the user. The liner allows users instant customization by applying the Cushion Liner over the positive and then baking it for 30 minutes. A gel durometer and contour provides additional control and support, and the liner is adaptable to most types of users.



The Liberty Liner from ALPS features a valve that is incorporated into the distal end of the liner, which allows the user to expel any air trapped between the liner and the limb.

- Thermoliner Locking Liner™ — Using the same capabilities as the Cushion Liner, the Thermoliner Locking Liner provides an adequate solution for difficult-to- fit patients with the convenience of a pin attachment.

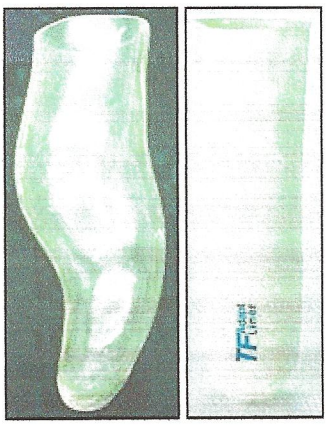
- Liberty Liner™ — The Liberty Liner features a valve that is incorporated into the distal end of the liner, which allows the user to expel any air trapped between the liner and the limb. It is helpful for patients who have poor manual dexterity, invaginations and fleshy residuals, all of which may cause air entrapment.

- Antimicrobial Liner™ — With all of the benefits of the Easyliner and Thermoliner, the Antimicrobial Liner has silver impregnated into the EasyGel. This acts as an antibacterial and antifungal agent, reducing odor and dermatological problems.

While discussing the applications of ALPS liners, McLoone noted their universal applications regarding patients who have problems finding a liner that fits and feels comfortable. "We find our liners most successful with patients who are hard to fit," he said. "The material has an extremely low modulus of elasticity, so the Easygel moves easily within the socket to reduce the shear forces that cause irritation to patients with sensitive limbs."

ALPS liners range in size from 10 cm to 65 cm in circumference, and are suitable for users of all activity levels. The liners are also adaptable to most types of users, and provide adequate support to the various anatomic structures of the residual limb.

Otto Bock HealthCare



While providing breakthrough patient comfort solutions to better manage residual limb health and socket fit is Otto Bock HealthCare's mantra, the company is one of the largest liner suppliers in the O&P industry. Offering liners in a variety of designs and materials, Otto Bock fills unique patient needs in the marketplace with such tried and true liners as their Silicone Gel Liner™, TechnoGel Liner™, Profile Liner™, Simplicity Liner™, Sirona Liner™ and AKquire Liner™.

Company officials said that their newest silicone gel liner, the TF Adapt Liner™, provides superior durability and reduces pistoning. Featuring an anti-pistoning matrix embedded in the silicone and not the cover, the device eliminates longitudinal stretch while still allowing for horizontal stretch to ease donning and doffing. The TF Adapt is designed with an extremely durable fabric, providing a

Otto Bock's newest silicone gel liner, the TF Adapt Liner™ (right), features an anti-pistoning matrix embedded in the silicone and not the cover. The device eliminates longitudinal stretch while still allowing for horizontal stretch to ease donning and doffing. The Custom Harmony Liner is pictured on the left.

long liner life for active users.

"The durability of the TF Adapt Liner is incorporated by using the same types of fibers used to make bulletproof vests," said Karen Lundquist, marketing communications manager for Otto Bock HealthCare. "They are especially effective for those who tend to hip hike due to longitudinal travel of the liner, or for whom consistent donning is an issue."

Also providing an integral facet to Otto Bock's liner operations are the Custom Harmony Liner and its accompanying Harmony Sleeve. Together, these products compose the Harmony Volume Management System. The Harmony Liner and Sleeve operate together with the Harmony Pump to create elevated vacuum between the liner and the socket wall. Not only does this elevated vacuum between the socket and the liner control volume, but it also ultimately helps the prosthesis become one with the user.

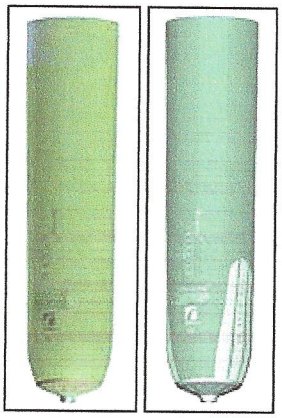
"The Custom Harmony Liner, made of urethane, is also ideal for those with unique residual limb shapes, sensitivity or scarring issues," Lundquist said. "It provides the most intimate fit possible, and can be based on a cast, measurements or a CAD drawing. The Custom Harmony Liner is available for both lower and upper extremity limb deficiencies."

All Otto Bock liners are available in a variety of sizes and work with all ages and activity levels. The company's silicone liners use a proprietary silicone that allows fabricators to vary both thickness and durometer anywhere the user chooses. This allows the inclusion of softer gel pads inside the liner so that bony prominences or areas susceptible to skin breakdown can be targeted before they become a problem.

Ossur

In the mid 1970s, Ossur company founder Ossur Kristinson was the first person to provide O&P patients with off-the-shelf silicone liners. Fast forward more than 30 years later, and today Ossur prides itself as a company whose key inventors continue to design products they themselves dreamed of as prosthetic users. Its second generation of silicone liners supports the motto of "Life Without Limitations," as Ossur's Icecross Dermo, Stabilo and Sport liners have proven to be skin friendly and to reduce the occurrence of dermatological problems associated with liner use.

"Most amputees have experienced improved comfort and function when fit with Icecross silicone liners," said Ian Fothergill, BSc, regional clinical manager for Ossur. "Icecross silicone liners are designed to eliminate movement between the prosthetic device and the residual limb of the amputee by controlling the skin and underlying soft tissue, while our locking and seal-in liners provide positive suspension and the elimination of pistoning. With these liners, we have focused on accurate size selection and materials that can comfortably stretch over a range of residual limb shapes."



Ossur's Icecross silicone liners contain "Active Skin Care" to combat some of the skin conditions that can occur as a result of long-term occlusion of the skin and the high loading required from prosthetic use. The Icecross Dermo is pictured on the left and the Icecross Stabilo is

Since the introduction of the first Icecross liners in 1986, Ossur have used silicone elastomers, chosen for their strength, durability and controllable durometer. The outer covers of the liners are predominantly made from a fabric called Supplex from DuPont, which was chosen for its high scuff resistance and high tear strength without compromising elasticity and comfort. The material acts as an interface between bony prominences and the hard socket wall, redistributing and minimizing any pressure peaks. Moreover, the gel characteristics of the liners also prove highly effective for reduction of peak pressures within the prosthetic sockets.

"Icecross silicone liners contain ingredients that we have called 'Active Skin Care'," Fothergill explained. These are primarily petroleum jelly and aloe vera — the petroleum jelly content helps the user maintain hydration of the skin beneath the liner, and the aloe vera reduces the irritation and inflammation of the skin. Together they combat some of the skin conditions that can occur as a result of long-term

occlusion of the skin and the high loading required from prosthetic use." pictured on the right.

Icecross liners are formatted to fit the majority of transtibial, transfemoral and upper extremity amputees. They are available in 19 sizes for transtibial amputees and 12 sizes and profiles for transfemoral amputees, and are adaptable for all ages and activity levels. A Seal-In Liner is also available featuring a hypobaric sealing membrane that provides a firm, comfortable suspension without an external sleeve. While each liner has been developed to yield optimal results with a variety of users and amputation levels, Fothergill said that great success has been found when the liner is used on amputees with excessive redundant tissue and those with excessive scarring or skin grafts.

For more information:

- www.easyliner.com
- www.eurointl.com
- www.freedom-innovations.com
- www.ossur.com
- www.ottobock.com
- www.owwco.com
- www.silipos.com

Editor's Note:

This story includes a small representative sample of individual manufacturers and products. O&P Business News does not intend to promote individual manufacturers or their products, nor to achieve an industry-wide consensus on the issue. Manufacturers contacted in developing this story were randomly selected. Additional manufacturers were contacted for information but had not responded prior to press time.