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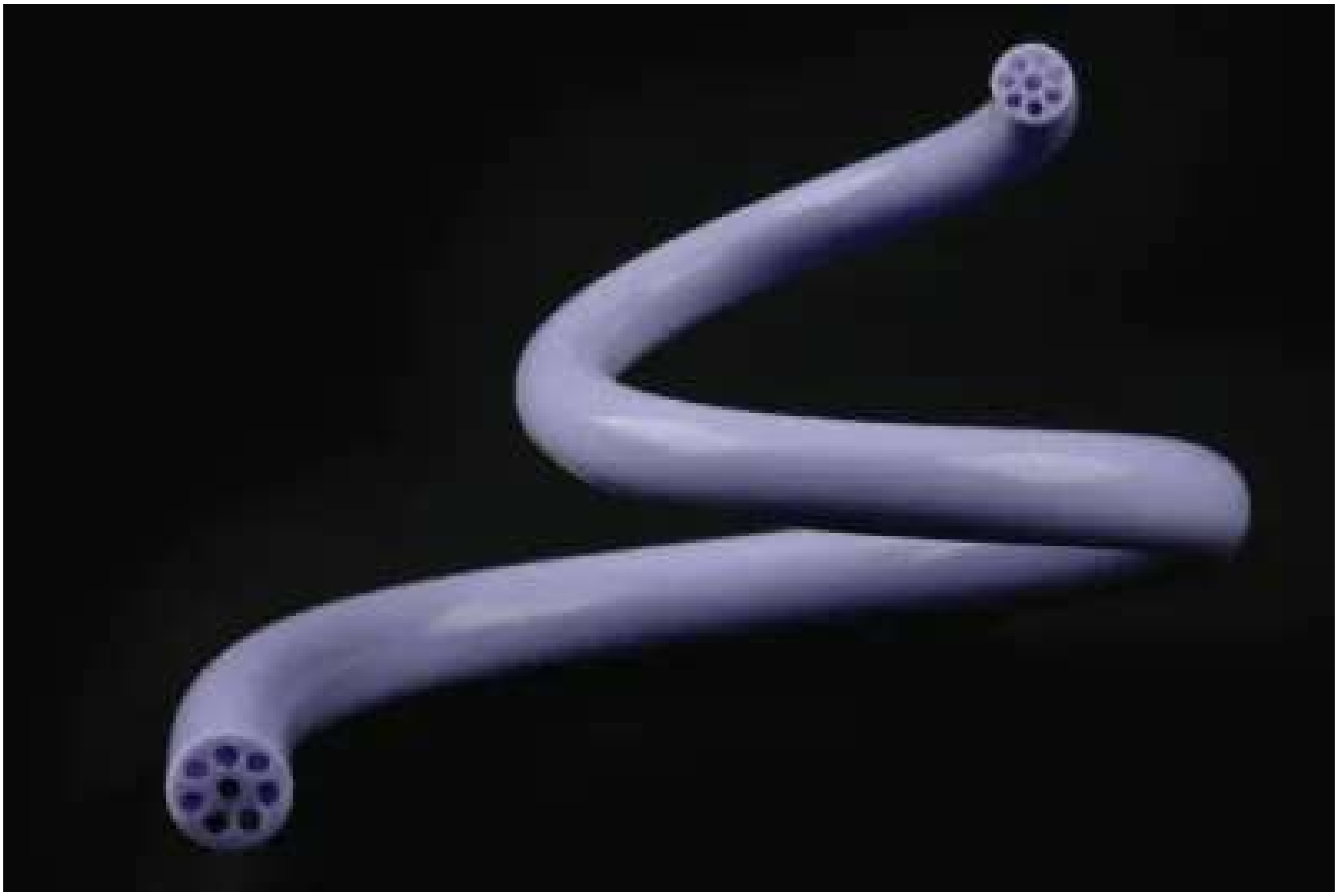
How These Engineered Extrusion Trends Can Improve Device Design and Patient Experience

Silicone tubes can be reinforced in a variety of ways, from polyester and stainless-steel braids for expansion-, elongation- and burst-resistance to spiral reinforcement with nylon monofilament for kink- and crush-resistance to keep fluid paths open. (Credit: Trelleborg Healthcare & Medical)

Hoses and tubes are extensively used within the healthcare and medical industry in a variety of applications, from wound drains and catheters to drug delivery and feeding tubes. Technology has moved far beyond the production of single, hollow tubes to multilumen extrusions that can incorporate stops, bumps, and varying thicknesses in a single design.

Significant benefits can be achieved by taking advantage of innovative manufacturing processes and the latest material options to reduce device developers' total cost of ownership while increasing component integrity. At the same time, manufacturing processes can improve patients' quality of life



Silicone tape, sheet, and ribbon can be extruded up to 152 mm/6 in. in width with a thickness down to 0.13 mm/0.005 in. (Credit: Trelleborg Healthcare & Medical)

by facilitating reduction in device size and weight, as well as incorporating multifaceted geometries, multiple substrates, and active pharmaceutical ingredients (APIs). Such improvements can enhance treatment in terms of safety and comfort and make wearable medical device options more appealing.

To facilitate the specification of these streamlined yet complex extrusions, key factors need to be considered. These factors will be outlined in this article along with material options concentrating on silicone extrusion technologies and application examples.

A LOOK AT THE MARKET

Why is the medical device market growing? Reasons for a predicted growth in the medical device market include:

- Fast aging populations and increasing life expectancy.
- More people looking for improved quality of life.
- Growing incidences of chronic disease.
- Rapid increase in the prevalence of infectious diseases.

- Rise in obesity.
- An increase in the number of surgical procedures and complex surgeries.

Silicone tape, sheet, and ribbon can be extruded up to 152 mm/6 in. in width with a thickness down to 0.13 mm/0.005 in. (Credit: Trelleborg Healthcare & Medical)

- Adoption of advanced technologies.
- Rising healthcare expenditure globally.
- Strong economic growth and increasing access to healthcare facilities in emerging countries.

Global market for medical devices. According to The Business Research Company, the global medical device market reached a value of nearly $456.8 billion in 2020. The market is expected to grow from $456.8 billion in 2020 to $662 billion in 2025 at a rate of 7.7 percent. The medical devices market is then expected to grow at a CAGR of 5.5 percent from 2025 and reach $863.2.4 billion in 2030. 1

This decline was mainly anticipated due to lockdowns imposed by governments across the world related to the COVID-19 pandemic, which hindered global supply chains, including in the medical device manufacturing industry. 1

Global market for hoses and tubing. The medical device market's overall growth is causing an increase in demand for medical tubing. According to Grand View Research, the global medical tubing market was estimated at $11.39 billion in 2020 and has an expected CAGR of 7 percent from 2020 to 2028. Additionally, tubing's growth can be attributed to the availability of cost-competitive medical-grade plastics; a surge in demand for single-use or disposable devices due to growing awareness of hospital-acquired infections and efforts to prevent them; and developing countries having increased access to healthcare supplies.

Key trends. To help detect diseases in the initial stages and mitigate treatment costs, a trend toward further development of diagnostic equipment is gaining momentum. An emphasis on preventing the spread of infection from one patient to another also is increasing.

Silicone tape, sheet, and ribbon can be extruded up to 152 mm/6 in. in width with a thickness down to 0.13 mm/0.005 in. (Credit: Trelleborg Healthcare & Medical)

Continuous innovation in drug-delivery systems is expanding demand for customizable tubes. In addition, innovations, such as intra cochlear drug delivery and photothermally triggered drug delivery, are expected to lead to growth in nano medical tubes.

Less-invasive medical procedures offer the advantages of lower cost, as well as quicker recovery times and shorter hospital stays for patients. These procedures are therefore increasing in importance compared to conventional surgical procedures, which in turn is increasing the market for tubing used to make such procedures possible.

The trend toward less-invasive procedures also places technical demands on the devices to be designed in increasingly smaller and complex ways.

Medical tubing applications. In terms of applications, the medical tubing market is categorized into bulk disposable tubing, drug-delivery systems, catheters, biopharmaceutical laboratory equipment, and other categories.

Stent tubes and implant-grade tubes are anticipated to boost market growth. Advancements in wound therapy, in which tubes are used to remove infectious materials and fluids, also is expected to drive growth in the sector.

Market by material. The medical tubing market is categorized in terms of materials into polyolefins, silicone, polyvinyl chloride (PVC), fluoropolymers, polycarbonates, and others. PVC is the most widely used thermoplastic material in medical tube manufacturing, but silicone is seeing significant growth.

The demand for PVC tubing is anticipated to increase owing to the rising demand for single-use presterilized medical devices, which are transparent, biocompatible, and offer high resistance to chemicals. PVC led the market and accounted for 29.5 percent of the global revenue share for tubing in 2020 while silicone, with its inherent suitability, in particular for implantable devices, is estimated to be the second-fastest growing segment.

APPLICATION EXAMPLES

Bioprocessing Flow Tubing

Application: Tubing to give a high-flow-rate discharge through a large-volume bottom outlet disposable biobag.

Issues:

- Desired flow rates were not being achieved.
- Tubing was collapsing due to large suction pressure.

Solution: Tubing wall was increased to 0.48 mm/0.188 in. from 0.32 mm/0.125 in., while maintaining the same inner diameter. The thicker wall prevented the tubing from collapsing, and the specified flow rates were met.

Central Vascular Access Catheters

Application: Multilumen tubing and liquid-injection overmolding connectors for central vascular access catheters.

Issue:

- Maintaining orientation of feeding lines.

Solution: Multilumen tubing and overmolded connectors utilized a combination of high-precision, liquid-injection molding and extrusion production techniques.

Orthopedic Tubing

Application: Extrusion used in an orthopedic additive-eluting medical device.

Issues:

- Outer diameter less than 0.012 in. required.
- Precisely control a specific elution curve of consistent concentration over a lengthened release time.

Solution: Close collaboration that started with the elution concept. Using a single material resulted in a narrow two-layer extrusion with the core serving as an eluting rod and an outer concentric layer that precisely regulates elution in MIS procedures. The entire cross section was under 0.012 in. Customer measurement fixtures were developed and validated with the process.

Implantable Neurostimulator

Application: Electrical pulses to the brain and spinal cord are used for chronic pain therapy and to treat disorders such as epilepsy, Parkinson's, and Tourette syndrome.

Issue:

- Leads must be very small while maintaining insulation properties to deliver the neurostimulating signals to precise locations.

Solution: Extremely tight tolerances were met with a microextrusion made possible with advancements in quality process control and monitoring systems. Diameters of ≤0.030 in. and required tolerances of 0.001 in. inner diameter, outer diameter, wall thickness, and concentricity to allow for assembly of the conductor ensure sufficient and consistent insulation along the length of the lead and minimize the overall size.

Pacemaker Lead

Application: Insulating, biocompatible extrusion carrying multiple conductors for a pacemaker lead.

Issues:

- A strain relief method was needed to mitigate risk of breaking due to dynamic loading.
- The multilumen extrusion design included more that 30 dimensions with tolerances of 0.002 in. or less.

Solution: Employed continuously twisted tubing process technology with custom tooling and measurement fixtures to validate the process capability of all required dimensions.

Heart Pump

Application: Cable jacketing.

Issue:

- Provide a biocompatible, protective layer to a cable assembly including several conductors, insulators, and strength members.

Solution: Developed and validated custom extrusion tooling in conjunction with a precise cure parameter window to apply a silicone jacket around the outside of the cable assembly without damage to internal cable components.

TUBING TECHNOLOGIES

Different processing options have led to groundbreaking ways of producing tubing. When customers partner with medical device component manufacturers that utilize the latest capabilities and technologies, they can create solutions that optimize the performance and usability of medical devices.

High-precision microextrusion and thin-walled tubing. Microextrusion processing performing below the submillimeter (0.1 mm) range employs modified equipment featuring innovations in extrusion head, tool, and screw designs. Microextruded, thin-walled tubing can be manufactured down to 0.05 mm/0.002 in. and with outside and inside diameters down to 0.25 mm/0.004 in., potentially for use in minimally invasive surgical (MIS) procedures.

Multicomponent extrusion. Multiple materials can be simultaneously extruded within the same tube to account for differing properties and media interactions. The most common example of this capability is the inclusion of a radiopaque stripe, which typically incorporates a barium sulfate-loaded silicone as the stripe used to locate the device in an x-ray or fluoroscope, but this inclusion can also be used to vary hardness of specific contact surfaces or to facilitate downstream assembly through color coding of lumen.

Extruded ribbon and film. Silicone tape, sheet, and ribbon can be extruded up to 152 mm/6 in. in width with a thickness down to 0.13 mm/0.005 in. Such ribbon can be supplied in spools with carriers and slip sheets or as punched seals or diaphragms to support sealing applications in devices such as pacemaker generator housings.

Reinforced and kink-resistant tubing. Silicone tubes can be reinforced in a variety of ways, from polyester and stainless-steel braids for expansion-, elongation-, and burst-resistance to spiral reinforcement with nylon monofilament for kink- and crush-resistance to keep fluid paths open. Reinforcement is customizable, and tubes can be made to specific precision tolerances.

Silicone tubing reinforced with polyester braid can also be used to resist abrasion under cyclic loading, such as in pacing leads. The outer covers can be pigmented if required. Care must be taken to verify that the mechanical properties of reinforcing materials are not compromised by the heat required to cure the silicone.

Jacketed wires and cables. Wire and cable assemblies up to 5.08 mm/0.2 in., such as those used to power implantable heart pumps, can be jacketed with one or more layers of silicone to precision tolerances. Such products can be supplied on spools or cut to length. Like reinforced tubing, care must be taken to verify that the mechanical properties of reinforcing materials are not compromised by the heat required to cure the silicone.

Custom profiles. Custom profiles often do not include lumen and are used to seal housing assemblies or in heart valve repair applications. Being nonsymmetrical, such cross sections can require longer development cycles and can be more difficult to measure while trying to maintain the extrusion's *free state*.

Platinum-cured silicones can eliminate the need for a secondary post-cure process, which is required for older peroxide-cured silicone systems. (Credit: Trelleborg Healthcare & Medical)

Twisted extrusions. This extrusion process produces continuously twisted tubing for use in applications in which implanted power or sensing cables require strain relief from repeated flexing and bending, such as with pacemaker leads.

The tube cross section typically consists of a center lumen and multiple outer lumens, with the twisting process causing the outer lumen to become spiraled around the center lumen. In this structure, wires fed through the outer lumen are less prone to dynamic flex failures because stresses are distributed more evenly to the multiple wires.

The process does not require the tubing to have a round outer diameter. And features, such as grooves, can be incorporated on the outer surface. Accurate verification of the spiral pitch requires translucent tubing and custom measurement techniques.

Bump tubing. Bump or tapered tubing is created by stretching the tube at a varying rate to produce tubing with a larger diameter at one end and a significantly smaller diameter at the other end. The process can be applied to plastics and elastomers, including silicone. The geometry is limited by the Poisson's ratio of the material during stretching in the green state.

Formed extrusions. Extruded tubing is designed to create complex paths, such as sinusoid shapes for flex and strain relief and to fit tortuous anatomy, or spiral shapes that might be used to soften contact within the bladder, for example. Measurement of such geometries in the extrusion's free state can be challenging and require custom manufacturing methods.

Bonded or overmolded stops. Stops can be bonded or molded onto tubing to lock it in place and keep it from rotating. The stops are typically added to peristaltic pumps for infusion, internal feeding, laboratory equipment, diagnostic equipment, and bioprocessing fluid transfer. The key advantage of peristaltic pumps is their disposable pump tubing. Only the tubing's inner diameter comes into contact with the fluid; therefore, there is no need to clean or flush the pump between uses.

Multilumen extrusion. Using this technology, numerous lumens or channels are produced as a single extrusion. More lumens mean more dimensions to control and measure, including the inner diameters and the walls between diameters.

High-precision vision systems with custom programming are often required to ensure quality. Downstream molding can incorporate overmolded connectors to separate the lumen into individual tubes.

Typical applications include catheters, electronic medical devices, analytical equipment, fluid transfer, drug delivery, and medical instrumentation.

Geometric transitioning extrusion. Geometric transitioning, or GeoTrans™, allows for silicone tubing to change the cross section during the extrusion process to eliminate molding and secondary bonding steps. Reducing the number of components and the bonding joints between them allows for a more hygienic design.

The GeoTrans technology is applied to custom applications with precision tolerances. To facilitate the development cycle for these highly customized extrusions, it is fastest to identify one cross section as critical and allow flexibility of other cross sections. Typical changes include:

- Changing the tubing inner diameter, outer diameter, or both to create tubing with two or more different cross sections.
- Bifurcation or converting a dual lumen extrusion into two single lumen tubes.
- Inclusion of channels to open internal fluid paths at locations along the extrusion length.
- Stopping one of multiple lumens to avoid the need for backfilling, such as when the lumen will be used for balloon inflation.
- Thinning a tube wall for a short section to drive specific balloon inflation, location, and shape.

Geometric transitioning single lumen. This technology, also called *off-ratio bump tubing,* creates two distinct tube cross sections with a near-step transition between them.

Tubing lengths are available in single transition (cross section A to B) or double transition (cross section A to B to A) options. Applications include custom-end assemblies, such as accommodation of connectors or fittings, and peristaltic pumps.

Foam extrusion. Closed-cell silicone foam offers custom mechanical characteristics by lowering effective durometer and providing additional cushion space. Silicone foam extrusion can be customized in a variety of sizes and cross sections with precision tolerances. Cell pore size and foam density can also be adjusted. Silicone foams are made from medical-grade HCR, platinum-cured silicone.

Measurement of foam materials can be less precise due to the natural variation of surfaces caused by cell formation that creates the lower density foam.

TUBING MATERIALS

Depending on the application, medical hoses and tubing are produced in a variety of materials, including plastics such as fluorinated ethylene propylene (FEP), Nylon, PVC, polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE); thermoplastic elastomers (TPE); and elastomers, in particular, silicone.

Silicone. Silicone is a key tubing material for medical devices, especially for implants. The unique characteristics of high-consistency rubber (HCR) silicones offer an uncured, green strength that allows for a variety of custom and complex processing techniques. Additional advantages include the following:

- It is proven to be inert and biostable, making it the gold standard in terms of biocompatibility.
- It is nonreactive with other elements.
- It can be platinum-cured for the highest degree of purity.
- Durometers can be easily altered.
- It allows for extended post-cure for lowest level extractables.
- It does not utilize leaching plasticizers.
- Certain formulations are suitable for long-term surgical implant.
- It is odorless, tasteless, and nontoxic.
- It possesses favorable physical and haptic attributes.
- It can be manufactured with a variety of textures.
- It can be sterilized by radiation, EtO, steam: 30 psi/2 bar at +123 °C/+253 °F.
- It resists temperature extremes with flexibility retention: from –54 ° to +204 °C/ from –65 ° to +400 °F; brittle point: –73 °C/–100 °F.
- It is processable in numerous ways, including molding, overmolding, sheeting, dipping, and extrusion, as well as in combination with other materials and substrates.
- It can include different fillers for specific applications.
- It offers exceptional permeability, allowing absorption of APIs.

Drug eluting. Silicone is often used for catheters, respirators, and implants due to its biocompatibility and biostability benefits; however, silicone is not immune to bacterial colonization.

One option to prevent tubing from transmitting bacteria is to impregnate vulcanized silicone with APIs. The silicone is immersed in the drug solutions, which can be absorbed into the material.

The APIs do not interfere with the cure chemistry of the silicone and are uniformly impregnated through the matrix of the silicone. Customizing the API concentration and adding release membranes enables a drug to be released at a constant rate. APIs can also be used to release a variety of drugs slowly, over longer periods, and focused at the site of need. For example, hormones and cancer treatments can elute through silicone.

Platinum-cured silicone. Platinum-cured silicones can eliminate the need for a secondary post-cure process, which is required for older peroxide-cured silicone systems. Platinum-cured silicone contains fewer volatile organic compounds and can be formulated to have faster cure times at lower temperatures.

Using this technology, numerous lumens or channels are produced as a single extrusion. More lumen means more dimensions to control and measure. (Credit: Trelleborg Healthcare & Medical)

Platinum-cured silicones can be formulated to bond with metals used in implants, such as titanium, stainless steel, and nitinol, and with plastics such as polycarbonate, polyester, and PEEK.

FACTORS TO BE CONSIDERED BEFORE SPECIFYING TUBING AND HOSES

Before designing tubing and hoses for medical devices, engineers should consider factors such as size, hardness, tear strength, elongation, surface friction, transparency, and visibility.

Size. Size is increasingly becoming a critical factor in the design of tubing as medical device developers seek to produce ever-smaller devices and less-invasive drug-delivery systems. Shrinking geometries and tolerances can push the limits of process control and create downstream challenges with testing, measurement, and assembly.

Hardness. Extruded silicone is commonly available in durometers from Shore A 20 to Shore A 80. As the durometer increases, tensile strength decreases, making it an important factor to prevent break failures in wound drains, for instance, which are put under significant tensile load when removed from the body.

Tear strength. Tear strength influences, for example, how difficult it is for a nick in a tube to propagate and is a consideration in situations in which the tube might be exposed to a sharp edge or for geometry with small internal radii. Lower-durometer silicones have significantly lower tear strength.

Elongation. Elongation properties relate to the elasticity of the tubing, which is a significant factor for balloon devices, for instance. Lower-durometer silicones have higher elongation properties.

Surface friction. When it is important for a tube to have minimal surface friction, the tube can be coated to decrease the material's inherent stickiness. For instance, a coating can reduce the forces required for deployment of an implanted or interventional device, like stents and balloons, or to facilitate assembly of tight fits in devices like pacing leads.

The coating or surface finish must be biocompatible if it is likely to come into contact with the body. Several coatings are available that bond well to silicone and meet compatibility requirements.

Transparency. Visibility to verify flow of media through a tube is important for certain types of devices, such as those carrying fluids into or out of the body. Silicone, for instance, is naturally translucent. However, certain silica fillers that increase durometer, as well as fillers such as barium sulfate ($BaSo_4$) and titanium dioxide (TiO_2), can reduce or eliminate transparency.

Visibility. Designers may wish to make a tube more visible within the body, to aid in guiding a device through the body when viewing it using an x-ray or fluoroscope, for example.

Barium stripes can be added to a tube to make it visible within soft tissue, while still enabling the fluid to be viewed to verify flow. A higher percentage of barium additive can be used to ensure that a tube can be seen through bone, such as to help a surgeon place a catheter in the spine.

There is a limit to the amount of radiopaque additive that can be incorporated and still render silicone processable by extrusion, however. Even the smallest additive amount can make silicone visibly opaque without offering sufficient radiopacity.

TUBING'S ROLE IN ENHANCING DEVICE DESIGN

Responding to rapid growth in the medical device market, medical device manufacturers are looking to innovative processes to enhance their products and meet patients' needs, including miniaturization and wearability.

Hoses and tubing manufacturing techniques are helping to support these new developments and improve patient quality of life with increased function and enhanced integrity and by enabling the incorporation of APIs.

To facilitate manufacturing these complex extrusions to client specifications and with user experience in mind, designers and manufacturers should work with an expert in hoses and tubing who can help identify and prioritize critical features relevant to the application and who can employ progressive technologies and processes to revolutionize medical device design.

REFERENCES

1. “*Medical Devices Market 2021 - By Type Of Device [http://www.thebusinessresearchcompany.com/report/medical-devices-market]* ,” Global Forecast to 2023, The Business Research Company, accessed Jun 1, 2022.
2. “*Medical Tubing Market Size, Share & Trends Analysis Report [http://www.grandviewresearch.com/industry-analysis/medical-tubing-market]* ,” 2020–2-28, Grand View Research, accesses Jun 1, 2022.

This article was written by Dan Sanchez, Product Manager, Trelleborg Healthcare & Medical, Paso Robles, CA. For more information, visit here [https://www.trelleborg.com] . A detailed white paper can be downloaded at here [https://www.trelleborg.com/en/healthcare/tools-and-media/technical-library/advanced-extrusion-whitepaper] .

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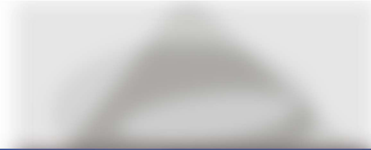

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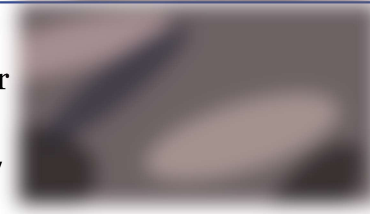

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