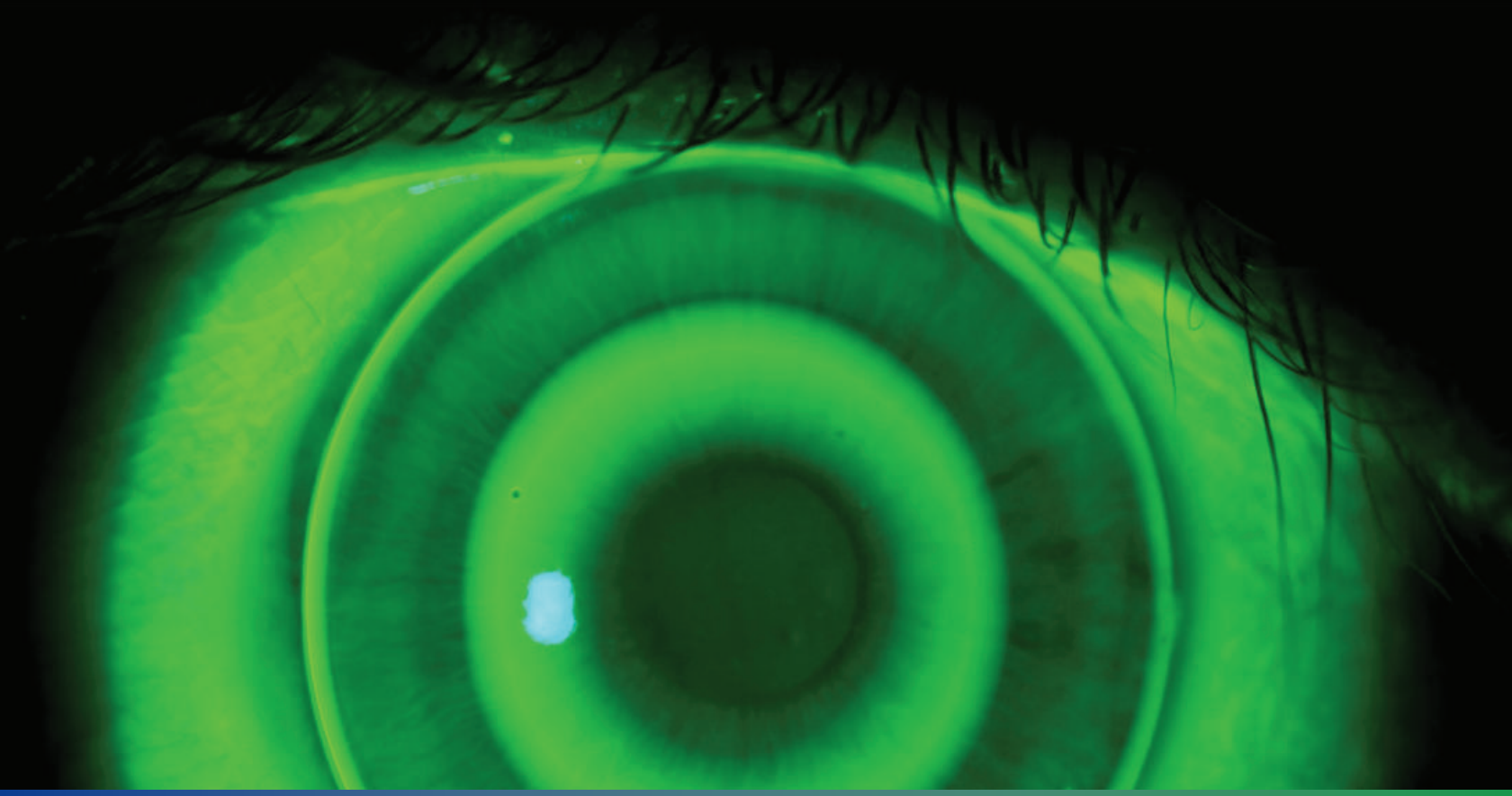

Welcome to the World of Siesta 100™

For overnight orthokeratology using Paragon HDS® 100

Siesta 100™

orthokeratology

Training and Certification Guide

TruForm OPTICS

Specialty Lenses Are Our Focus

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Siesta 100™ Training and Certification

WELCOME

Thank you for your interest in Siesta 100™ for the temporary reduction of myopia through the process of orthokeratology.

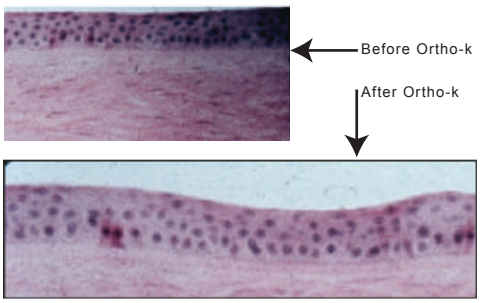
The information in this booklet will provide a clear understanding of the Siesta 100™ lens design, how to fit the product, and by successfully passing the Certification Test at the conclusion of this booklet, you will be Certified to prescribe Siesta 100™ in your practice.

The expert consultants at TruForm Optics are available to assist you at 800-792-1095.

Corneal Shape Change Through Redistribution of Tissue

In orthokeratology with Siesta 100™, the change in corneal shape results from forces exerted on the tear film between the back surface of the lens and the cornea, causing a gradual and steady compression and possibly a redistribution of fluids and epithelial cells under the lens from the center toward the periphery.

Specifically, the central corneal epithelium becomes thinner as a result of positive pressure under a flat central curve of the shaping lens, while the mid periphery becomes thicker due to the negative created by the annular tear pool under a steeper second or reverse curve.



FDA Approved

Siesta 100™ is FDA approved to treat up to 3 Diopters of myopia, with or without up to 1.50 Diopters of refractive cylinder. Siesta 100™ is manufactured in Paragon HDS® 100 (Dk 100[1] ISO/ANSI) and in a distinctive Yellow tint, which ensures the prescriber is receiving the Paragon lens material they expect.

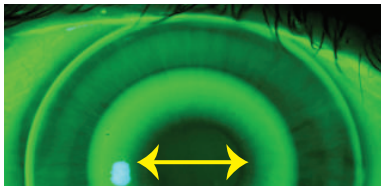
Approved for daily wear, extended wear and overnight orthokeratology, Paragon HDS® 100 delivers a high dk material to support eye health.

1 (cm2/sec) (mL O2) / (mL x mm Hg) ISO/ANSI Method, ISO 9913-1

Siesta 100™ is plasma treated to enhance initial comfort and wettability.

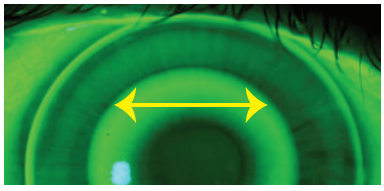
Design Elements of Siesta 100™

Base Curve



Calculated to target emmetropia, the base curve is flatter than the central corneal radius, which provides positive pressure resulting in compression of the central corneal epithelium. Unlike the base curve in traditional GP designs, the base curve in Siesta 100™ is used only to flatten the cornea to treat myopia, and is not considered a fit factor. Generally, the back optic zone diameter (BOZD) ranges from 6.0 to 8.0mm and creates a treatment zone of 5.0mm or more.

Reverse Curve



An important element to a successful fit is lens centration and central applanation. Both are accomplished by controlling sagittal depth, utilizing the reverse curve. The reverse curve is 3-to-5 diopters (or more) steeper than the base curve. The reverse curve forms a tear reservoir surrounding the base curve, providing an area for the epithelial cells and intracellular fluid to collect. This zone, comprised of one or more curves, is typically 0.6 to 1.0mm wide.

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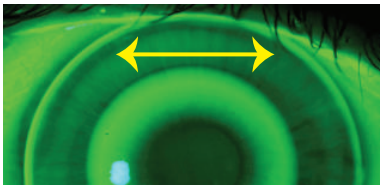
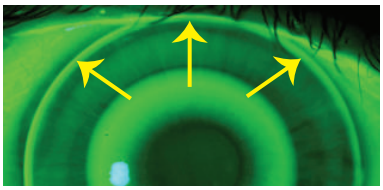
Alignment Curve(s)



The alignment curve is flatter than the reverse curve and should closely align the peripheral cornea to provide light bearing to aid in lens centration. To improve lens centration, the fitting relationship can be modified by altering radius of the alignment curve(s). It is 1.0 to 1.5 mm wide.

Peripheral Curve and Edge Lift



The peripheral curve and edge lift is flatter than the alignment curve to provide an edge lift that is adequate for overall lens comfort and movement, along with tear and debris exchange.

Lens Power and Diameter

The lens power is +0.75D, which incorporates a standard over-correction of +0.75D. This is necessary due to the small amount of regression which takes place upon lens removal in the morning. The standard diameter size is 10.6mm.

Patient Selection

The most successful Siesta 100™ candidates are moderate to low level myopes, whose corneal shapes have "e" values of 0.5 and higher, an apical radius measurement between 40.00 and 46.00 diopters and corneal diameters greater than 11.00mm.

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Patient Selection Considerations

Avoid patients with higher amounts of myopia, low corneal eccentricity measurements and flat corneas. Against-the-rule astigmatism greater than 0.75D can also be problematic, in that this reshaping process may induce even higher amounts of against-the-rule astigmatism.

Previous GP and PMMA lens wearers should remain out of their lenses until corneal and refractive measurements have stabilized, often 2 to 4 weeks or more.

Evaluate the pupil size accurately in both normal and dim illumination. Depending on the amount of attempted myopic reduction, the expected treatment zone is usually 5mm to 6mm in size.

Therefore, patients with pupils greater than 5mm in normal illumination and/or greater than 6mm in low illumination may not be suitable candidates. Large pupils may result in halos, glare or peripheral distortion in dim lighting conditions.

In addition, it is advisable to ***avoid*** patients that have:

- active ocular infections
- severe corneal irregularity from injury or surgery
- keratoconus or a corneal dystrophy
- limbus-to-limbus astigmatism

Limbus-to-limbus astigmatism should be avoided because it may result in a less effective ortho-k procedure as the fitting relationship is altered in the periphery and lens rocking may occur. Visually, the net result is that full myopic reduction is not achieved or the treatment regresses quickly.

Compliance, Lens Care and Maintenance

Patient compliance is an important factor in the success of ortho-k treatment.

The patient should be instructed to use only the recommended approved GP lens care products with their lenses.

It is important for the wearer to check that the lenses are moving before attempting removal.

Instill several drops of rewetting solution just before sleep and upon waking.

Instruct patients to contact your office for proper guidance on managing bound lenses.

In some cases, the wearer may need a DMV® lens remover.

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Parameter Selection and Lens Ordering

Siesta 100™ can be fit empirically and does not require an investment in a diagnostic set.

The expert consultants at TruForm will design your Siesta 100™ lenses based on the following information:

- K Readings
- Refraction
- "E" Value
- HVID

If you utilize a corneal topography as part of your Orthokeratology fitting process, the TruForm consultant will provide you with instructions to export the topography maps during the ordering process.

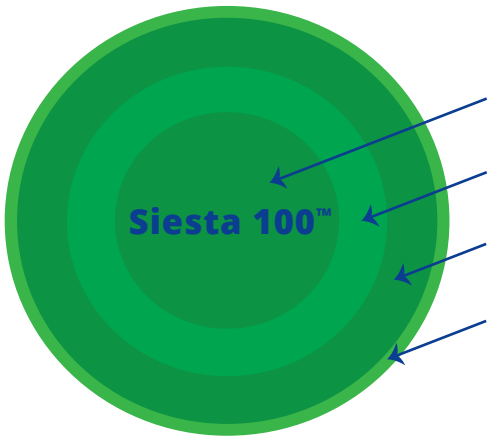
In-Depth Look at Siesta™ 100

Now that we have discussed some general principles regarding orthokeratology, let's look at the details of how Siesta 100™ works.

Siesta 100™ is a dual compression lens with the base curve and alignment curve providing the two compression zones. The base curve will determine how much myopia is reduced and the alignment curve will control centration.

The base curve provides a compression factor of an additional 0.75D. This over correction is pre-calculated for the small amount of regression that takes place upon removal lens in the morning.

The reverse curve provides a relief area for tissue redistribution. The peripheral curve's primary purpose is to help in tear exchange.



Base Curve
- determines amount of myopia to reduce

Reverse Curve
- relief area for tissue redistribution

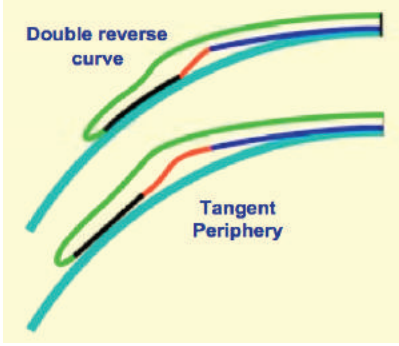
Alignment Curve
- controls lens centration

Peripheral Curve
- controls edge lift for tear exchange

Double Reverse Curve vs. Tangent Periphery

There are two general types of ortho-K lenses on the market today: the double reverse curve and the tangent periphery lenses. Both lens designs have four distinct functional zones: a base curve zone, a zone to bring the back surface of the lens back to the corneal surface, a secondary compression zone and a peripheral zone.

The major difference in these two designs is the alignment or secondary compression zone. The 4-zone double reverse curve has a more aligned fit resulting in increased surface area touch which will enhance centration. Conversely, the tangent periphery style lenses (shown graphically in the adjacent drawing) only touch at one point, since it is a tangent or line being fit to a curve. This will decrease the amount of surface area in contact with the cornea.



The double reverse design has more design flexibility due to the curved nature of the alignment curve. This is the concept the Siesta 100™ design is based upon.

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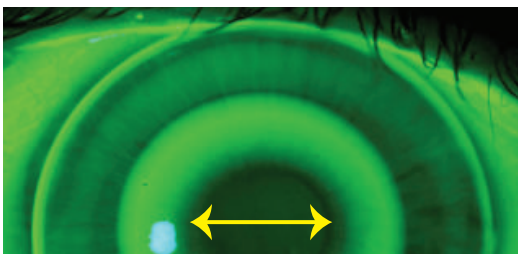
Dispensing Visit

Once you have verified the lens parameters, you are ready to dispense the lenses.

Insert the lenses and describe to the patient the expected adaptation process, if any. Check the visual acuity with the lenses on, then do an over-refraction while the lenses are in place. The over-refraction should be Plano.

Next, evaluate the Fluorescein pattern. The lens should be centered over the base curve treatment area.



Ensure there is adequate tear film touch in the periphery, and proper edge lift.

Have the staff instruct lens application and removal. Consider dispensing a DMV® to remove the lenses, as Siesta 100™ lenses are larger than a standard GP lens and can be more difficult to remove with traditional removal techniques. Advise the patient to apply a drop of lubrication solution before the lens is applied to provide a thicker film for the lens to rest on, thus decreasing the chance for lens adhesion.

Schedule a visit for the next morning when the patient should return still wearing his or her lenses.

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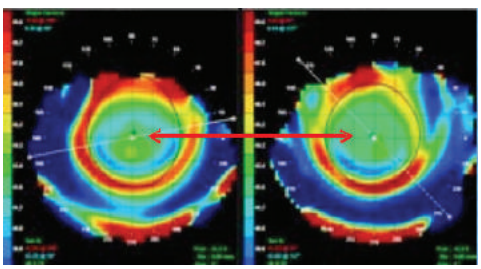
First Morning Visit

On the next morning visit, begin by evaluating the lens position and movement, in particular checking for lens adhesion. If the lens is not moving freely or if there is central corneal staining, review the use of the lens care products with the patient. Often, if the patient takes a long time to apply the lens, the lubricating solution will wash out, so advise the patient to put the lubricating solution on immediately before lens application. If adhesion or central staining is still present on subsequent visits, use a more viscous solution.

Next, remove the lenses and check the patient's unaided visual acuity. Consider checking both eyes together by first showing the 20/200 line and then going down one line at a time. This way the patient gets positive reinforcement on the vision improvement. Then check the acuity of each eye separately.

Perform a refraction. Don't be surprised if there is not a sharp end-point refraction especially on the first day, particularly if there is any central disruption of the corneal surface.

Take topographical maps and compare them to the pre-fit measurements. The lens should be centered over the base curve treatment area.



If the fluorescein pattern and/or corneal topography evaluation does not reflect a centered lens position, call your TruForm consultant to discuss.

Managing Daytime Vision During the Initial Treatment Period

Patients should be informed of a 7-to-14 day initial treatment period, which is the time frame required for the patients cornea to be fully molded.

Regression during the initial treatment period is to be expected and managing the patients daytime vision with disposable soft contact lenses or reapplying their Siesta 100 lenses should be discussed ahead of the fitting process.

Managing the patients expectations throughout the entire process is key in the success of their overall experience with orthokeratology.

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Possible Adverse Effects

Patients should be advised to discontinue lens wear and call your office if they experience any of the following:

- pain
- discomfort
- excessive tearing
- decreased vision
- foggy vision
- halos
- photophobia
- redness

Orthokeratology with Siesta 100™ should also be discontinued if you observe any corneal hypoxia or staining greater than Grade 2.

Subsequent Follow Up Visits

At the conclusion of the first morning follow up, answer any patient questions and schedule the next appointment in one week at the end of the day. While the one-day visit is in the morning, on future progress checks it is best to evaluate the patient later in the day to test how the vision treatment is holding throughout the day.

At the one week visit, check the topography and uncorrected acuity, perform a refraction and then evaluate the eye with the slit lamp.

At this point the uncorrected vision should be in the 20/20 to 20/25 range and holding during all waking hours. The treatment will be complete in most cases at this point. During upcoming office visits you will be looking for consistency in visual acuity and topographical findings.

If a problem is present, call your TruForm Optics consultant to discuss, and schedule another visit in a week to see if the problem is still present.

Unless the patient presents with acute discomfort or pain, only make a change if the same problem is present during two consecutive visits.

Make sure the patient brings their lenses with them at every visit. While an on-eye lens evaluation is not usually necessary, it will save time on those rare occasions when it is indicated.

Repeat the evaluations performed at the one-week visit during the one, three and six month progress checks.

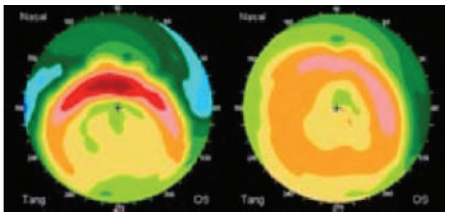
Trouble Shooting

Call your TruForm Consultant to review any case prior to making a lens change.

Common Problems

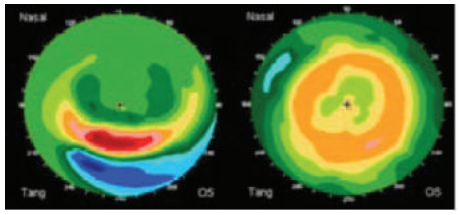
If there is an inadequate amount of myopic reduction, flattening the base curve would be appropriate. Also, too small of a treatment zone can be helped by increasing the optical zone.

Inferior Positioning = Loosen Fit



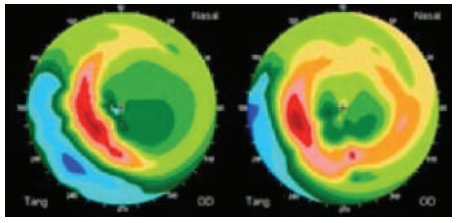
The most common change is to loosen the lens when it is positioning inferiorly. This will give the upper lid more grab to raise the lens.

Superior Positioning = Tighten Fit



A high riding or superior fit is just the opposite. In this case the lens needs to be tightened.

Lateral Decentration = Increase OAD



Lateral riders need more surface area in the alignment curve so this area is widened, primarily by increasing the overall diameter.

Siesta 100™ orthokeratology

Siesta 100™ Certification Test

Provide your practice information in the field below. Record your answers using the answer key below. A passing score is 12 or more correct answers. E-mail or fax (PAGE 7) the Siesta 100™ Certification Test to: info@tfoptics.com | fax: 800-522-8533

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PRACTICE INFORMATION

Practitioner Name

Practice Name

Address

City, State, Zip

Phone

E-mail

Record Your Answers

	A	B	C
1	○	○	○
2	○	○	○
3	○	○	○
4	○	○	○
5	○	○	○
6	○	○	○
7	○	○	○
8	○	○	○
9	○	○	○
10	○	○	○
11	○	○	○
12	○	○	○
13	○	○	○
14	○	○	○
15	○	○	○

1. In Orthokeratology, corneal tissue is distributed in which direction?
A. Periphery towards center **B.** Center towards periphery **C.** Tissue does not change

2. What is the upper limit of the approval range for Siesta 100™?
A. -4.00D **B.** -3.00D **C.** -6.00D

3. What is the appropriate size of the treatment zone as result of successful fit?
A. 2-3mm **B.** 3-4mm **C.** 5-6mm

4. What is the ideal ROL (Refraction-Over Lens) in an appropriate Siesta 100™ fitting?
A. -0.75D **B.** +0.75D **C.** Plano

5. The following type of astigmatism will remain untreated after Siesta 100™ treatment.
A. With-the-rule **B.** Lenticular **C.** Against-the-Rule

6. Before removing the Siesta 100™ lens in the morning, the patient should be sure their lenses are:
A. Moving freely/not adhered **B.** Clean and free of coating **C.** Well centered

7. What is the suggested limit of corneal with-the-rule astigmatism to fit with Siesta™ 100?
A. 1.00D **B.** 1.50D **C.** 0.75D

8. What is the length of time for the initial treatment period?
A. 3-to-5 days **B.** One month **C.** 7-to-14 days

9. A lens with appropriate treatment zone that results in inadequate overall treatment will require:
A. Increase diameter **B.** Increase sagittal depth **C.** Decrease sagittal depth

10. Which of the following are contraindications for Orthokeratology?
A. Lid Margin Disease **B.** Irregular Astigmatism **C.** Both A and B

11. Corneal Topography plays a key role in which of the following phases of a Siesta 100™ fit?
A. Lens selection/design **B.** Follow-up/management **C.** Both A and B

12. The correct treatment formula when calculating the Base Curve is to have a target power of:
A. +0.75D **B.** -0.75D **C.** -1.50D

13. The most effective way to make slight reduction adjustments in sagittal depth is to:
A. Steepen alignment curve **B.** Reduce the BOZR **C.** Flatten alignment curve

14. Excessive bubbles underneath a well-centered lens typically indicate a lens with:
A. Insufficient sagittal depth **B.** Lateral decentration **C.** Excessive sagittal depth

15. A lens that decenters laterally needs the following adjustment in order to center over the pupil:
A. Flatten alignment curve **B.** Increase diameter **C.** Decrease diameter

E-mail or fax this page to:

info@tfoptics.com

fax: 800-522-8533

At TruForm Optics, we focus on what we do best:

"Deliver eye care professionals the finest quality, specialty GP lens designs."

TruForm is a family owned business with headquarters in the Dallas/Ft. Worth, Texas area. We are long time members of the Contact Lens Manufacturers Association (CLMA) and proud recipients of the CLMA Seal of Excellence. The Seal of Excellence is awarded to laboratories whose lenses meet or exceed applicable industry standards as determined randomly by an independent testing service.

You can trust TruForm Optics for your specialty GP lens needs.

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Siesta 100™ is manufactured in

CooperVision® Specialty EyeCare Paragon HDS®100

07/2020