Boston™
GP Lens Manufacturing Guide

Boston™ II Material

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BAUSCH + LOMB

Boston™
GP Lens Manufacturing Guide

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Manufacturing Process for Boston™ Materials

Introduction

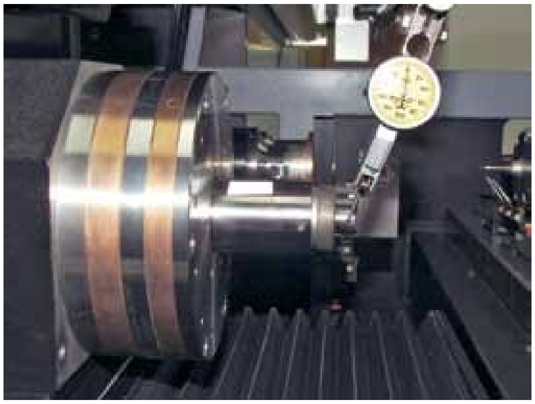
It is recommended that manufacturing of Boston materials into finished lens products be accomplished using the process listed in this guide with some variation due to your equipment differences.

It is important that any GP contact lens manufacturing process produces the minimum stress to the plastic possible. Excessive stress applied during manufacturing will cause warpage and/or stability problems. Solvent in an ultrasonic unit for deblocking and/or cleaning is not recommended as this can also cause lens stability problems.

Process

The steps described should be within the capabilities of all manufacturing sites. With the development of new, more complex GP materials and advanced lens designs, attention to manufacturing details to achieve product quality and consistency is critical.

Lathe Set-up and Calibration



The lathe is the heart of the lens manufacturing system. Therefore it is important that the lathe is operating at the highest level of performance. If the lathe set-up and calibration are incorrect, then all other operations in the manufacturing system will be negatively affected.

In order to maintain this high level of performance, the lathe must be calibrated correctly. Some of the critical areas of lathe set-up and calibration are: diamond tool height, spindle RPM, slide movement and axis alignment. These items must be set and maintained with precise accuracy at all times. Always refer to the lathe manufacturer's recommended maintenance and set-up procedures for the lathe you are using.

Inside Lathing

Fixation of the button for cutting the concave (base curve) surface can be achieved with either a closed collet system or by blocking the button and using an open collet system. Both systems will be discussed.

Closed Collet System

A collet of 0.5 inch (12.7mm) capacity is used for all Boston™ products. The pressure of the collet on the lens material button is a critical factor in manufacture. Excessive collet pressure will cause base curve warpage and/or stability problems. The collet closure mechanism must be adjusted for minimum pressure on the button. If the system is not adjustable, then the use of an open collet system should be considered.

Note: Collets having a 0.040 inch (1.016mm) depth have been seen to produce some lenses with slight toricity. This toricity may be due to lathing in a shoulder diameter for blocking and making a fully edged base curve product simultaneously, but this may not be the only reason for the induced toricity. If you are using this size collet depth and your lenses have slight toricity at final inspection, we recommend that the buttons be blocked on arbors and an open collet system used. Other collets with greater depths have been used and no toricity has been detected at final inspection.

Open Collet System

Fixation of the button can be achieved by blocking the button onto a flat-topped arbor or plate. **Note:** the temperature of the blocking medium should never exceed 167°F (75°C). It is important that the arbor or plate used for blocking the button be made of solid, sturdy material such as brass, Delrin or stainless steel. **Hollow arbors are not acceptable.** Arbors of this type can allow excessive collet pressure to be transferred to the button and do not sufficiently support the button during cutting. This can cause base curve warpage and/or lens stability problems.

Note: When blocking Boston XO_2™ material, water soluble wax must be used.

Cutting the Concave Surface

CNC lathes are the industry standard for cutting traditional symmetrical base curve geometries as well as secondary and peripheral curves. With some CNC lathes, more sophisticated aspheric and asymmetrical shapes can be cut. It is also possible to cut lens diameter during the base curve cutting operation, and cutting the edge profile is also an option with some lathes.

Base curve cutting is a critical step in the lens manufacturing process because this is where the fitting characteristics of the lens are produced. Any errors during this process will create a lens that does not fit and perform as expected.

The technician can enter the cutting parameters by using the lathe computer key pad, or with added software bar coding can be used, the latter being much quicker as well as reducing the possibility of entry errors. The use of CNC lathes not only produces high quality surfaces but also provides more accurate and consistent lens production.

While spindle speeds for base curve cutting varies, we have found that a spindle speed of about 7000 RPM produces the best surface quality which contributes to the best polishing times. Lathe spindle speed can be checked easily by placing reflective tape on the spindle and checking it with an electronic tachometer.

High temperature is a factor in reducing diamond tool life and can induce stress into the material that can affect lens wetting, stability and clinical performance. Cooling the tip of the diamond tool with a continual concentrated jet of compressed air combined with a strong vacuum to remove the swarf that accumulates during cutting helps to optimize the lens surface conditions and will help in extending diamond tool life.

Cutting depths should be 0.50mm to 0.75mm for rough cutting, using recommended feed and speed rates for your lathe model. The feed rate should be slow and steady to avoid surface irregularities. The recommended cutting depth for the final cut is 0.05mm to 0.10mm. Once again the feed and speed rates should be those recommended for your lathe model and should be performed slowly and steadily to help reduce polishing time to a minimum.

Lathe Settings Tested in the Boston Lab		
Spindle speed	7000-8000 RPM	
Rough cut depth	0.50mm-0.75mm	
Rough cut feed rate	DAC : 4.5	Optoform: 100mm/min
Finish cut depth	0.05mm-0.10mm	
Finish cut feed rate	DAC: 1.5	Optoform: 25mm/min

Polishing the Concave Surface

Polishing the base curve involves the use of radius tools covered with cloth or some kind of molded tool. Bladder tool polishing is also an accepted method.

At the Boston™ products manufacturing facility we use custom molded silicone tools covered with cloth. This custom molded silicone tool when covered with a recommended cloth produces excellent surface quality. The tool is made by injecting the silicone material in liquid form into a mold. After the silicone has cured the molded part is removed from the mold and placed on a metal base. The tool can then be covered with an approved cloth and secured with an O-ring.

One of the advantages of using a bladder polishing system is that one tool is used to polish most radii. Some have found this polishing system works well for reverse curve designs such as those used in orthokeratology. Single tool polishing can also be a cost saving system.

Soft tool polishing of any kind should only be used on surfaces cut on CNC lathes with air bearing spindles. This is because soft tools will not correct for geometry or optics that were inadequately produced by a less precise process. The lathe generates the shape and optics of the lens surface. Soft tool polishing is only used to remove the lathe rings and buff the surface. For this reason polishing times should be kept to a minimum with soft tool polishing. If other lathes are used, then hard tool polishing methods should be used.

The polishing machine should be capable of rotary and oscillatory movement. Spindle speeds should be 800 RPM to 1000 RPM for all Boston™ materials, with 2 to 4 oscillations every 10 seconds. The weight over the spindle should never exceed 10 ounces (280 grams). This weight should be centered directly over the spindle. The position of the part being polished should be positioned 0.5mm forward or behind the center of the spindle. The oscillation distance will vary depending on lens design and diameter. A good starting set-up would be 5.00mm.

Whatever polishing system is used the cycle time should never exceed 2 minutes. Polishing tools should be kept wet with polish and never allowed to run dry. Frequent application of polish during the polishing cycle and a clean filtered water rinse during the last few seconds of the cycle will help produce high quality surfaces.

Care should be taken to use only cloth made for the optical industry. Some cloth purchased at the local fabric store is treated with a chemical that forces water to run off the surface. The recommended cloth made for the optical industry allows water to instantly be absorbed. Use of cloth that has been surface treated might result in lens surface damage and poor clinical performance.

The choice of polish is left to the lens manufacturing facility. While many polishes are available, only those approved for GP lens manufacturing should be used. Some that are used successfully are ALOX 721, XPal, $SILO_2$ Care and Boston™ polish. Without exception polish containing solvents, alcohol, ammonia or silicone oils should not be used. These and other harsh chemicals added to polish will damage the lens surface and cause poor clinical performance.

Polisher Settings Tested in the Boston Lab		
	Six spindle oscillating	Larsen bladder type/green bladder type with microcloth
Spindle speed	800 (+/-100) RPM	50% RPM setting
Oscillation speed	4 strokes/10 seconds	60% oscillation setting
Oscillation distance	6.50mm	3.5-5.0mm stroke
Polish type	XPal, ALOX 721 or equivalent	
Polish Time		
Blend	Base curve	Front curve
20-30 seconds	30-45 seconds	Not to exceed 2 minutes

Base Curve Inspection

Inspecting the base curve after polishing helps to identify defects and allows the base curve to be recut or repolished, thereby saving material and production cost. It also provides the opportunity to track and fix production problems.

Without exception it is recommended that surface inspection be performed using a 20X microscope to identify scratches, lathe rings, incomplete polishing, and surface mottling. Use of a 7X or 10X loupe to inspect

Nietz Radiuscope, Polychem

surfaces is not sufficient to allow detection of surface irregularities. Only the use of 20X magnification will reveal surface irregularities or degradation that can lead to poor clinical performance when the lens is worn.

Base curve radius and optics inspection can be performed using conventional manual radiuscopes or one of the newer auto-radiuscopes. The use of an auto-radiuscope has the advantages of efficiency and objectivity. Some models also provide more information regarding surface shape and lathe calibration which can not be gathered from a manual instrument.

Checking Boston™ Envision™ and Boston MultiVision™ Blanks

For fabrication, Boston™ Envision™ and Boston MultiVision™ blanks can be taken from the package and inspected for central radius. To ensure correct measurement, the blank must lie perfectly horizontal. This will ensure, after centration, that the axis of the curve is perpendicular to the radiuscope optical axis.

The next step is to take center thickness. The lab should take special care in order not to scratch the surface of the button during this step. Due to the unique design of Boston™ Envision™ and Boston MultiVision™, the front curve calculations should only be performed using software provided by Bausch + Lomb. The software prompts you for the following inputs:

Base Curve (actual)
Lens Power (actual)
Diameter (pre-edged are diameter specific)
Lenticular Optical Zone (1.5mm less than diameter is recommended)
Center Thickness (see chart for standard thickness)
Edge Thickness (0.12mm recommended)

Blocking the Base Curve Blank (button with finished base curve)

Blocking of the base curve blank should be done with a compound that has a working temperature of 167°F (75°C) or less. We have obtained excellent results with water-soluble wax. Our preferred method for blocking Boston™ material is with water-soluble wax, due to the absence of solvents in the cleaning process.

We recommend these valuable tips for working with water-soluble wax:

- Keep unused wax in a storage area with desiccant or in a "dry box." This is especially important where humidity is high.
- Heat and melt only enough wax to last for the day's production. Some water-soluble wax tends to break down and lose important hardening and holding properties if left heated for extended periods of time.
- Heat and melt the wax only during lens production.
- It is best to control the wax thickness. A thin, controlled wax layer will allow the blocking arbor to add support to the lens during processing.
- When using a thin, controlled wax layer it is important to make sure that the crowns (top) of all blocking arbors are smooth and free of dents and other damage. The dents and damage can transfer into the lens and appear as aberrations and/or distortions in the finished lens.
- A reduction in the depth of the rough cut to no more than 0.70mm and a reduction in rough feed rate to 3.5 (DAC) will help reduce the separation of the lens from the wax during cutting.
- If the lathe software permits, using a pyramid-stepped-type cut for the rough cut will help reduce the separation of the lens from the wax.
- When using Delrin-tipped blocking arbors, be sure the surface of the Delrin has been lightly sanded with fine sandpaper or emery cloth. This will aid in making the wax stick to the arbor and lenses will deblock cleaner.
- When cutting lens designs with extremely flat or extremely steep base curves, it might be helpful to cut arbors with a crown radius more closely aligned to the base curve. A wax thickness that is extremely thin or extremely thick might cause aberrations and/or distortions in the finished lens.

- Temperature of the blocking wax is important. To protect the material, it should be no more than 167°F or 75°C. Lower is better. Be sure to consult the wax distributor to determine the best working temperature of the wax being used. Always monitor the wax temperature during production. Overheating the wax can destroy the working properties of the wax.
- Air cooling of the base curve blank after blocking will help prevent potential lens stability problems by minimizing exposure to elevated temperatures. However, be sure the cooling occurs evenly around the part being blocked because uneven cooling can cause the part to become distorted, resulting in poor finished lens quality.
- Brass blocking arbors need only to be warm to the touch and should not be overheated. A better alternative is to use blocking arbors tipped with Delrin that do not require heating.

Front Surface Lathing

Front surface cutting is critical to the lens manufacturing process because this is where the lens power, lens thickness, and other important optical characteristics are put into the lens.

It is important that the appropriate software be used when manufacturing lenses from Boston™ materials. This is especially true when cutting designs such as Boston™ Envision™ and Boston MultiVision™. Use of correct refractive index as well as accurate lens parameter data will help ensure that the lenses produced will provide high wearer satisfaction and that production yields and costs will be satisfactory.

Lathe calibration should always be a high priority when cutting front surfaces. If the lathe is not calibrated and maintained correctly, the lenses cut will be defective. Some of the critical areas of calibration are diamond height, lathe lateral, radius, and center thickness.

Lathing the outside curves should be done with slow steady sweeps with rough cutting depths not to exceed 0.75mm and the finishing cut no less than 0.05mm and no more than 0.10mm in depth using spindle speeds of approximately 7000 revolutions per minute. See *Cutting the Concave Surface* for the recommended settings.

Note: Most Boston MultiVision™ lenses will need lenticulation in order to arrive at the correct 0.14mm edge thickness. When lenticulation is required, a front surface lenticular zone diameter of 8.1mm should be used.

Additional Boston Multivision™ Information

This information can be used in lens design and front curve lathe operating software.

The axial edge lift (AEL) for Boston MultiVision™ is 0.12mm at 9.6mm diameter. This applies to all base-curve radii values. The sagittal depth for Boston MultiVision™ is listed below. This applies only to 9.6mm diameter.

Base	Sagittal Depth (in mm)
7.0	1.779
7.1	1.743
7.3	1.708
7.3	1.675
7.4	1.643
7.5	1.613
7.6	1.583
7.7	1.555
7.8	1.527
7.9	1.501
8.0	1.476
8.1	1.451
8.2	1.428
8.3	1.405
8.4	1.383

Outside Polishing

A number of polishes have been tested and work well with Boston™ materials, including XPal, ALOX 721 and other commercially available polishes. A variety of different media can be used to polish the outside curve. Our tests were completed using a Delrin cup/sponge/cloth combination sold through Sterling International and other major suppliers. The polishing time should not exceed 2 minutes. Keeping the media clean and wet throughout the process will decrease the occurrence of defects on the lenses.

The Wilmington manufacturing facility uses XPal mixed in the following manner:

Ingredients:

950 gms (± 25 gms) of XPal powder
4,000 mls of sub-micron filtered water

- Pour the filtered water into a clean pitcher, beaker, or other suitable vessel and insert the mixing wand into the water.
- Set the mixer to the highest speed possible without foaming the mixture or causing the mixture to overflow the container.
- Add the XPal gradually and mix for approximately 10 minutes.
- After mixing is complete, let the polish sit for 10 minutes, allowing for heavier particles of XPal to settle out of the mixture.
- Pour the polish into a clean container through a funnel which is fitted with five layers of wire mesh with 120-micron openings until 400 to 500 mls (about 1/8th of the mixed polish) remains in the bottom of the mixing container; dispose of this remaining polish.
- Fill dispensing bottles from the container of filtered polish as needed. It is best to fill as few bottles as possible, as the polish will settle in the dispensing bottles when not in use.
- Keep the filtered polish under the mixer, agitating continuously, until more is needed to refill dispensing bottles. Filter the polish as it is poured into the dispensing bottles.
- Clean the filtering funnel and mesh with water after every use.

This batch size polishes approximately 1,000 base curves. You may need to adjust the batch size to better suit your volume.

Lens Deblocking

Use of an ultrasonic cleaning unit containing a mixture of water and a detergent such as Alconox is an efficient method for removing the lens from the blocking arbor. This method helps to reduce solvent exposure time required to clean pitch or wax from the lens surface. To assist in this deblocking method, it is recommended to make a bubble under the edge of the lens by gently lifting the edge in one small area of the lens. It is also important to keep the liquid in the ultrasonic tank cold (40°F or 4°C).

Note: The use of solvent in an ultrasonic unit should never be implemented for deblocking Boston™ GP lenses. This process will damage the lens surface and can lead to wetting and other clinical performance problems. Solvent used in an ultrasonic unit can also release fumes that might be irritating to operators working in that area.

Prying the lens from the blocking tool is not recommended. This might cause chipping, breakage, and/or lens warpage. The preferred method is to block with a water-soluble compound which eliminates the need to use solvent. When using a water-soluble blocking compound, the deblocking method is generally the same as previously explained. It is best to consult with the distributor of the water soluble compound regarding the recommended deblocking method.

When using Boston™ Water Soluble Wax, you should not use ultrasonic deblocking, because this might damage the lens surface. The recommended deblocking method is to hold the blocked lens under gently running warm water. Within a few seconds the lens can be lifted off the blocking tool.

Initial Lens Cleaning

Note: When using water-soluble wax, it is not necessary to use solvent in the cleaning process. All other cleaning steps should be followed.

Lenses processed using conventional blocking pitch or wax should be cleaned with Medi-Sol or an equivalent solvent used sparingly to remove any residue after deblocking. We recommend Medi-Sol (available from Sterling) or equivalent citrus solvents such as Fluorosolve (Paragon Vision Sciences) and Wax-Sol (Polychem). We do not recommend the use of lighter fluid or petroleum-based solvents.

Cleaning liquids should be dispensed from individual containers. Dipping the lens from one container to another is not recommended because this will cause cross-contamination of the cleaning liquids. Cross-contamination will reduce the effectiveness of the cleaning process. Dispense a small amount of solvent onto a clean tissue. Using a gentle blotting action, remove pitch or wax residue from the lens surface. Lenses should not be rubbed because rubbing might scratch the lens surface. Solvent exposure should be no more than ten to fifteen seconds. Lenses should not be soaked in solvent.

The lens must then be cleaned with Boston™ Laboratory Lens Cleaner or a similar cleaner approved for GP lenses. This step will remove any solvent residue. The lens must then be thoroughly flushed with clean water. Filtered, distilled or deionized water is preferred. Dry the lens with a clean, dry tissue. The lens must be deposit-free after cleaning in order for good wetting qualities to exist.

Note: It is strongly recommended that water-soluble blocking compound be used to avoid any contact with solvent. If water-soluble blocking compound is used, solvent cleaning is not necessary.

Finishing (secondary and peripheral application and edging)

Secondary and peripheral curves can be applied either by the lathe or by using diamond-plated radius tools. Polishing these curves can be done either using a flexible silicone-type peripheral polishing curve system or by covering radius tools with polishing cloth. A ski-type blend is recommended where the transition from the base curve to posterior peripheral curve forms a smooth continuum.

Boston™ Envision™ Design

Normal peripheral and secondary curves should not be applied. Some edge finishing must be done so that the proper edge profile is achieved. The lab must roll in the edge to complete a well-tapered round edge. To reduce the potential of lens adhesion it is very important to elevate the inside edge of Envision during the edge finishing process. This can be achieved by two methods and these are outlined below.

1. By using a steeper than normal approach angle of the lens edge to the edging sponge or pad. This will tend to remove more material from the inside edge of the lens.
2. By using a blending tool to insert a small bevel (or rim) on the inside of the edge prior to the edge rounding/profiling step. The blending tool you select should be 2.0mm flatter than the base-curve radius of the Boston™ Envision™ lenses you are finishing. The bevel you create should be no more than 0.2mm in width. Once this is achieved the remainder of the edging process may commence. Also, care must be taken as to produce as little stress in the lens as possible during the entire edging procedure.

Note: Neither Step 1 or 2 are applicable for pre-edged Boston™ Envision™. The pre-edged Boston™ Envision™ edge contour should be finished in the normal manner.

Edge Polishing

Edge finishing should be done to produce a well-tapered round edge. Refer to the ANSI standards for acceptable edge shapes and for all measurement tolerances. During the edging process, care must be taken to produce as little stress in the lens as possible.

Only appropriate types of sponges should be used in order to avoid surface problems that could lead to poor clinical performance such as non-wetting, depositing and discomfort. Sponges with wide cell structures are stiffer and more abrasive. This will not produce edges that are smooth and even.

Aggressive polishing, over-polishing or dry polishing will all contribute to mottling and/or burning of the lens surface. Most mottling is found in the area of peripheral curves or edges; however, mottling can occur anywhere on the lens surface where there is excessive polishing or the material is allowed to overheat when applying too little polish.

Although manual edging is acceptable, most labs are using auto-edging machines to provide uniform and consistent edges time after time. Care must be taken to use modest spindle speeds and adequate amounts of polish to avoid burning the lens surface. Machine set-up is important in order to achieve the correct edge profile. The set-up will vary depending on the type of machine being used. On all machines it is important to be sure the lens edge is deep enough into the sponge to get the required results.

Note: Upper vacuum pressure with Boston™ Envision™ product should be no more than 23 PSI (1.6 BAR) with auto-edge finishers. Higher levels of pressure may cause curve distortion.

Lens Inspection

- It is strongly recommended that inspection of the front and back surfaces and the edge be performed with a 20X microscope to ensure that there are no areas of mottling, scratching or other degradation of the lens surfaces. The edge should be inspected for shape and chipped or broken areas.
- Measurement of lens center thickness should be performed using an analog or digital thickness gauge capable of measuring to 0.01mm or less.
- Inspection for lens power and optical quality as well as prism should be performed using a lensometer or vertexometer. Some labs are using auto lensometers to measure lens power. This can be helpful in measuring multifocal and other specialty lens designs. The Boston MultiVision™ lens distance power should be checked using a lensometer or vertexometer as with any other lens. The add power is progressive in the periphery and will not appear as a distinct power zone.
- Lens diameter measurement should be performed using a V gauge, loupe with a scale or some other instrument with a measurement system.
- Inspection of lens optic and lenticular zones should be performed using a loupe with a scale or some other magnifying instrument with a measuring system.
- Measurement of base curve radius and optical quality should be performed using a radiuscope or interferometer. Some labs are using auto radiuscopes that also measure lens center thickness. All inspection equipment should be calibrated on a regular basis to ensure accurate and consistent measurements.

Final Lens Cleaning

Before shipment all lenses should be cleaned using Boston™ Laboratory Lens Cleaner and a clean water rinse to ensure that all residue from manufacturing and handling is removed. Lenses that have not been properly cleaned will have poor clinical performance. It is also important that the lens cases that are used for lens shipment be thoroughly cleaned to prevent lens contamination. Lenses shipped in dirty lens cases can result in poor clinical performance.

Plasma Treatment

Lenses manufactured from Boston™ materials can be plasma treated. Please refer to the plasma treatment section of this document.

Lens Design Parameters

Boston™ II, Boston™ IV, Boston Equalens™, Boston Equalens™ II, Boston XO™, Boston XO_2™:

Minimum Center Thickness for Minus Lens	
Lens Power	Center Thickness
Plano	0.18mm
-1.00	0.17mm
-2.00	0.16mm
-3.00	0.15mm
-4.00	0.14mm
-5.00	0.13mm
-6.00	0.13mm
-7.00	0.13mm
-8.00 and higher powers	0.13mm
For plus powered lenses, our recommended junction thickness is 0.18mm.	

Boston ES™, Boston EO™:

Center Thickness Chart For Minus Lens		
Lens Power	Standard	Thin
Plano	0.18mm	0.15mm
-1.00	0.17mm	0.14mm
-2.00	0.16mm	0.13mm
-3.00	0.15mm	0.12mm
-4.00	0.14mm	0.10mm
-5.00	0.13mm	0.10mm
-6.00	0.12mm	0.10mm
-7.00	0.11mm	0.10mm
-8.00	0.10mm	0.10mm

Boston ES™:

Ultra Thin Design Center Thickness Chart For Minus Lens	
Lens Power	Ultra Thin
Plano	0.14mm
-1.00	0.13mm
-2.00	0.12mm
-3.00	0.10mm
-4.00	0.08mm
-5.00	0.08mm
-6.00	0.08mm
-7.00	0.08mm
-8.00	0.08mm

Materials Specifications*

	Boston™ II	Boston ES™	Boston™ IV	Boston™ Equalens™	Boston EO™	Boston™ Equalens™ II	Boston XO™	Boston XO_2
Permeability (ISO/Fatt) cgs units †	12	18	19	47	58	85	100	141
Rockwell Hardness	119	118	117	117	114	114	112	100
Shore D Hardness	85	85	84	82	83	81	81	78
Refractive Index	1.471	1.443	1.469	1.439	1.429	1.423	1.415	1.424
Modulus (MPa)	1800	1900	1600	1600	1600	1300	1500	1160
Toughness (MNm/m^3)	3.0	3.4	2.8	2.8	2.6	0.8	2.6	2.7
Silicon Content	10-12%	5-7%	14-16%	13-15%	5-7%	9-10%	8-9%	12-13%
Wetting Angle (captive bubble)	20°	52°	17°	30°	49°	30°	49°	38°
Dynamic Contact Angle (advanced/ receding)	58°/57°	52°/50°	58°/57°	59°/56°	62°/60°	59°/56°	59°/58°	50°/40°
Specific Gravity	1.13	1.22	1.10	1.19	1.23	1.24	1.27	1.19

* All data on file

† $x10^{-11} cm^3 O_2 (cm)/[(sec.)(cm^2)(mm\ Hg)]$@35°C

Manufacturing Guide for Large Diameter Lenses

Introduction

Manufacturing of Boston™ large diameter buttons into finished scleral or semi-scleral lens products should be performed using the process listed below, with some variation due to equipment differences.

Process

All of the steps described below are within the capabilities of manufacturing sites with two-axis lathes. Careful attention to all details of each step will assist in the achievement of maximum yields and product satisfaction.

Inside Lathing

Closed Collet System

Most Boston™ large diameter products are available with and without a 0.5 inch (12.7mm) shoulder or step. A closed step collet of 0.5 inch (12.7mm) capacity can be used for the shouldered product, utilizing the shoulder that is part of the 17mm button. The pressure of the collet on the button is a critical factor in manufacture. Excessive collet pressure can cause base curve warpage and/or stability problems. The collet closure mechanism should be adjusted for minimum pressure on the button. If the system is not adjustable, then the use of an open collet system should be considered.

Open Collet System

Fixation of the button can be achieved by blocking the button onto a flat-topped arbor or plate with blocking pitch or water-soluble wax. When using the open collet system, the arbor is held by the collet rather than the button. In this way the collet pressure is on the arbor and not the button. The open collet system can be used with either the shouldered or non-shouldered product.

Note: Caution should be taken when using blocking medium for open collets: The temperature should never exceed 75°C (167°F).

Cutting the Concave Surface

Due to the large diameter of the button and the combination of radius and depth of cut, the type of lathe used is a consideration. A lathe with a rotary cut sequence will have limitations. When cutting lenses with steeper base curves, the tooling on the lathe will begin to make contact with the edge of the lens blank before the final cut is completed. It is also likely that a rotary type lathe set up for cutting lenses from 0.5 inch (12.7mm) buttons will have clearance problems between the tool mounting block and the spindle when cutting the larger 17mm buttons.

Because of these limitations it is recommended that scleral and semi-scleral lenses be cut using a two-axis lathe. When using a two-axis lathe, the arrangement of the cutting tools on the lathe will need to be examined to ensure that there is adequate clearance for the larger button.

Consideration should also be given to the design of the diamond cutting tools. It might be necessary to order tooling with narrower (45 degree) included angles to accommodate the fact that some semi-scleral lenses have very steep sides. This angle should be small not only from the top (looking down at the tool), but also from the side. This means that the shank might also need to be modified. Tools with caps can also present a clearance problem.

Spindle speeds for base curves will vary between different types of lathes, but our laboratory's best results were obtained at approximately 7000 to 8000 RPM for symmetric surfaces. A rough-cut depth of 0.50mm to 0.75mm should be used. The final cut should be slow, steady, and of a 0.05-0.10mm depth.

Polishing the Concave Surface

A number of polish products can be used when polishing scleral lenses: X-pal, Alox –721, Boston™ Professional Cleaning Polish or equivalent. Also, a variety of polishing tool materials, such as the ones listed or an equivalent, can be used: Brass radius tools covered with micro-cloth, a soft silicone polishing lap covered with cloth (CR-39 cloth or micro-cloth), or an air bladder polishing flexible lap, such as the type used in the Larsen AL-01 single-spindle polisher.

In order to accommodate the large diameter, it will be necessary to increase the diameter of the polishing tool and/or adjust the polishing machine stroke. In some cases it might be necessary to perform a two-step polishing process, where the central portion of the lens is polished in the conventional manner and the periphery is polished with a large diameter soft tool (something like the sponge cone tool sold by Polychem).

Blocking for Front Surface Cutting

Blocking of the Boston™ materials should be done with a compound that has a working temperature of 75°C (167°F) or less. We have obtained excellent results with water-soluble wax and Kerr Dental Impression Compound Red No. 1 or an equivalent. Our preferred method for blocking is with a water soluble wax, due to the non-use of solvents for cleaning the lens.

Air cooling of the lens blank after blocking will help prevent potential lens stability problems by minimizing exposure to elevated temperatures. Brass blocking arbors need only to be warm to the touch and should not be overheated. A better alternative is to use blocking arbors tipped with Delrin that do not require heating.

Due to the large diameter of scleral lenses, it is recommended that an arbor with a larger diameter be used. A diameter in the range of 12.0mm to 14.0mm should be used.

It might be necessary to modify the blocking machine to accommodate the larger button.

When blocking with water-soluble blocking compounds, it is important to control the thickness of the compound between the lens blank and the arbor. Refer to the manufacturer's recommendations for details regarding the thickness of the compound layer.

Outside Lathing

Spindle speeds for front curves will vary between different types of lathes, but our laboratory's best results were obtained at approximately 7000 to 8000 RPM. Rough cuts should not exceed 0.75mm in depth, and the finishing cut should not be less than 0.05mm nor exceed 0.10mm in depth.

Generally the tool clearance issues associated with base curve lathing of large-diameter lenses are not a problem when cutting front surfaces. For this reason, it might be possible to cut the front surface with a lathe that utilizes a rotary table. This will depend on the lathe being used and the design being cut.

Outside Polishing

A number of polish products have been tested and work well with scleral lenses: X-pal, Alox–721, and Boston™ Professional Cleaning Polish or equivalent. When polishing the outside curve, it is recommended to use tools such as the cloth covered flexible tool system (the Delrin cup/sponge/cloth combination) sold through Sterling International and other major suppliers. The polishing time should not exceed 2 minutes. Keeping the media clean and wet throughout the process will decrease the amount of defects on the lenses. Depending on the lens diameter being polished, it might be necessary to adjust the stroke on the polishing machine.

Lens Deblocking

Lenses may be deblocked in an ultrasonic cleaning unit. Do not use solvent in an ultrasonic tank. The solvent can damage the lens plastic, which may result in wetting and other problems. A solution of water and a surfactant can be used. It is necessary to keep the solution in the ultrasonic tank cool for best results.

If using a water-soluble wax, careful attention to the manufacturer's recommendations should be used regarding ultrasonics.

Initial Lens Cleaning

Lenses should be cleaned with solvent to remove any blocking wax after deblocking. Solvents that can be used are Medi-Sol Optical solvent or an equivalent. The lens must then be cleaned with the Boston™ Laboratory Lens Cleaner or an equivalent and then thoroughly flushed with clean filtered water. The lens must be deposit-free after cleaning in order for the lenses to have good wetting qualities.

Note: If water-soluble wax is used solvent cleaning is not necessary.

Lens Finishing

Edge finishing should be done to produce a well-tapered round edge. Refer to the ANSI standards for acceptable edge shapes and for all measurement tolerances. During the edging process, care must be taken to produce as little stress in the lens as possible. Most conventional edge polishing methods can be used with scleral and semi-scleral lenses.

Lens Inspection

We strongly recommend the use of a stereo microscope set at 20X magnification for surface and edge inspection. It is our experience that the use of a microscope permits easy detection of irregularities that may not be evident when using a 7X or 10X loupe.

Other inspection instruments might need to be modified to accommodate a large diameter lens. It might be necessary to use a loupe or equivalent to measure lens diameter, since most V gauges only measure to about 11 mm. If a micrometer is used for measuring the lens diameter, great care should be exercised not to chip or compress the edge of the lens.

Final Lens Cleaning

All finished lenses should be cleaned with Boston™ Laboratory Lens Cleaner and rinsed with clean filtered water. This should be done after final inspection and just prior to packaging.

Packaging

It will be necessary to use a lens case that is appropriate for the large diameter of the lens. Most lenses manufactured from 17mm buttons will fit in deep-well wet cases.

Note: If there is a need for fenestration in your large-diameter lenses, the buttons can be purchased with fenestrations predrilled.

Fenestrated buttons

Plasma Treatment Procedure for Boston™ Materials

Process

All of the process steps described are within the capabilities of manufacturing sites with an AST PJ Bench-top Plasma System. Careful attention to all details of each step is recommended to achieve the best results.

System Requirements

- AST PJ Bench-top Plasma System, consisting of:
  - 8 inch diameter, 10 inch long Pyrex reaction chamber
  - 300 watt RF generator
  - 1 mass flow controller (50 sccm)
  - Automatic RF matching network
  - 10.6 cfm pump
  - Programmable logic controller for controlling all system components
- Vacuum pump, charged with Fomblin Oil, with a mist filter; exhausted to outside air*
- Extra dry oxygen gas (99.6% pure)
- Two stage oxygen regulator with accurate pressure delivery at 10 psig
- Hose with 1/4 inch OD with good chemical stability and pressure rating of at least 100 psi
- Computer with RS232 connection and with the PS-PJ application loaded
- Lens holders and Pyrex lens tray

***Note:** The AST PJ Bench-top Plasma System must be vented. Check local codes for proper venting.

Procedure

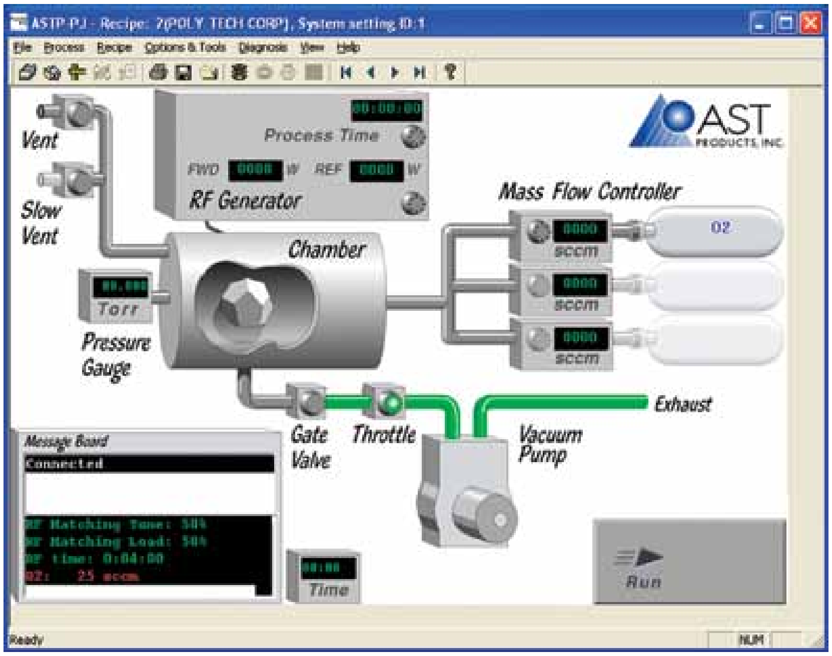
Note: It is recommended that two empty cycles be run after the system is first powered on so as to completely purge the system. Use the standard procedure for plasma treatment, but leave the chamber empty.

1. Turn on the vacuum pump (Figure 1). **Note:** Follow the manufacturer's recommendations for proper pump operation and warm-up.(Check with local codes regarding proper venting.)
2. Turn on the oxygen gas (Figure 2) and set the pressure regulator to 10 psig.
3. Turn on the AST PJ Plasma System (Figure 3).
4. Turn on the computer. Establish communication between the computer and the Plasma System by double clicking on the PS-PJ icon. The PS-PJ software will start–the system is now ready to operate.
5. Place lenses to be plasma treated in the lens holders. Lenses can be plasma treated in batches ranging from 1 to 20 lenses.

Figure 1. Vacuum pump power switch

Figure 2. Oxygen gas pressure regulator

Figure 3. AST PJ Plasma System power switch



6. Place the lens holders with the lenses on the Pyrex lens tray noting the location of each lens. Place the tray in the plasma chamber and close the chamber door.

7. Using the PS-PJ software, check the maximum settings by clicking on ***File*** in the upper right hand corner of the window and choosing ***Max Settings*** from the dropdown menu that appears. Check to make sure that the settings are configured as listed below:

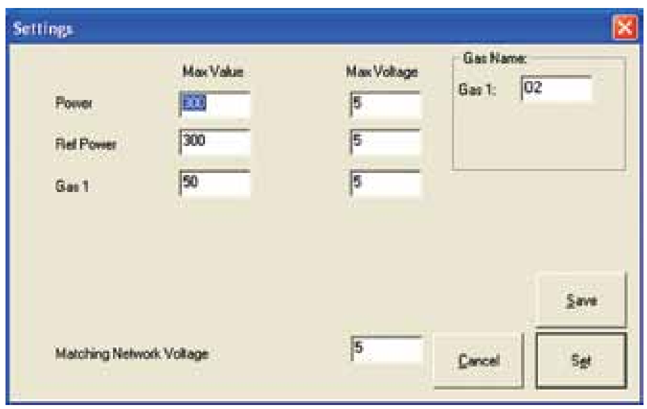
   a. Power
      - Max Value: 300
      - Max Voltage: 5

   b. Ref. Power
      - Max Value: 300
      - Max Voltage: 5

   c. Gas 1:
      - Max Value: 50
      - Max Voltage: 5

   d. Matching Network Voltage: 5

   e. Gas 1 Name: O_2



8. Using the PS-PJ software, check the system parameters by clicking on ***File*** in the upper right hand corner of the window and choosing ***System*** from the dropdown menu that appears. Check to make sure that the system parameters are set as listed below:

   a. Base Pressure: 0.1 torr

   b. Pump Time: 900 sec.

   c. Reflective Power Alarm: 15 watts

   d. RF Warning: 10%

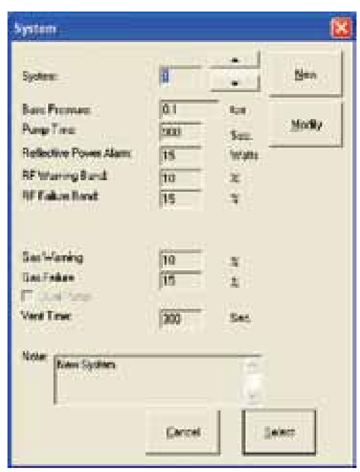
   e. RF Failure: 15%

   f. Gas Warning: 10%

   g. Gas Failure: 15%

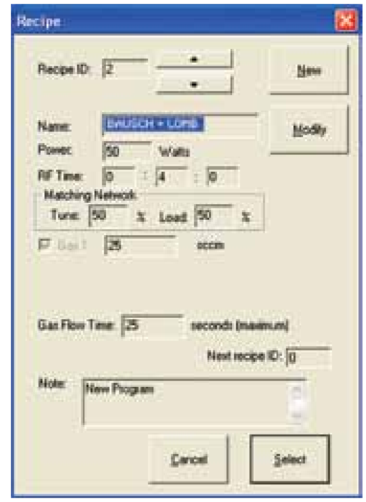
   h. Dual Pump checkbox: Unchecked

   i. Vent Time: 300 sec.



Plasma Treatment

When you are certain that the parameters are set correctly, click on the ***[Select]*** button to return to the main window.



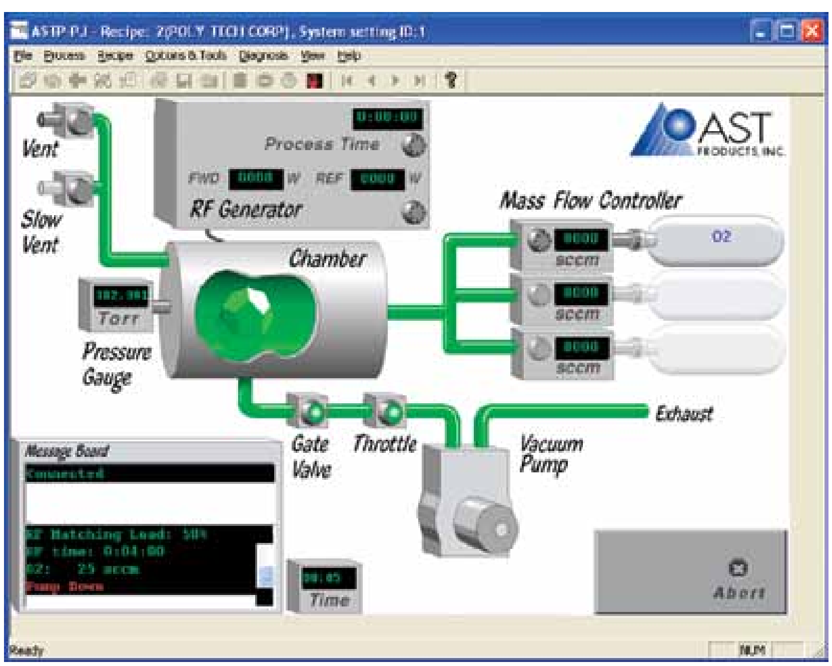
9. To begin the plasma treatment of the lenses, click on ***File*** again and choose ***Recipe*** from the dropdown menu. Choose the recipe with the parameters listed below:
   a. Power: 50 watts
   b. RF Time: 4.0 min. (0:4:0)
   c. Matching Network:
      • Tune 50%
      • Load 50%
   d. Gas: 25 sccm
   e. Gas Flow Time: 25 sec. (max)

When you are certain that the parameters are set correctly, click on the ***[Select]*** button to return to the main window.

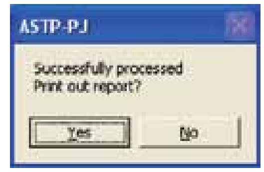
10. Go to the ***Process*** menu and click on ***Start.*** A ***Batch Information*** box will appear where the ***Lot Number, Size*** and ***Operator*** can be entered. After this information has been entered, click on ***[OK]***. The selected recipe will execute.

11. During the plasma treatment process, progress will be displayed in the main window. The area labeled ***Message Board*** will display the current step that is being executed.

12. The following steps will be automatically executed by the software:
    a. Air will be evacuated from the chamber. The display marked ***Pressure Gauge*** will show the current pressure in the chamber.
    b. Oxygen will fill the chamber. The amount of time until the chamber is full is displayed in the box marked ***Time***.
    c. The RF generator will run for the specified amount of time, plasma treating the lenses. The status of this process can be viewed in the box marked ***RF Generator.***
    d. The chamber will vent for the specified number of seconds, returning to normal atmospheric pressure.



13. At the end of the process, the PJ System will vent back to atmospheric pressure and the door can be opened. A box will appear on the computer screen that tells the operator that the batch was successfully processed. ***Print Out Report*** will also appear in the box; click ***[Yes]*** to print the report. If you wish to save the report to disk, click on ***File*** and choose ***Save Report*** from the dropdown menu. Enter the ***File Name*** and click on ***[Save].***



14. Once the plasma treatment has been completed, remove the tray with lenses from the chamber. Place the treated lenses in the appropriate lens containers. Wet shipping is recommended for plasma treated lenses.

Plasma Treating Boston™ Lenses with the Diener Tetra-8 Plasma Chamber

Testing

These recommendations were based on results obtained from plasma treating Boston materials with a Diener Tetra-8 plasma chamber. Sample lenses were treated under various conditions and the optimal settings were determined by measuring front and back surface sessile drop contact angle. It was found that the results were within specification and were comparable to the previously tested AST PJ Plasma System. No adverse lens reactions were observed in this testing.

Equipment Configuration

The test unit was a Diener Tetra-8 plasma chamber equipped with a 300 watt RF generator. The test system did not include a control PC. The system was supplied with extra dry oxygen gas (99.6% pure) at 10 psig. The system was exhausted to the outside.

Recipe

The recommended settings for the Diener Tetra-8 plasma chamber are as follow:

Power:	200 watts (66%)
Gas Flow:	200 sccm
RF Time:	2 minutes

All other chamber settings should be made as recommended by Diener documentation. Vent time should be adjusted such that the contents aren't displaced by the movement of air in the chamber and will vary depending on the configuration of the exhaust system used.

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