PROFESSIONAL FITTING AND INFORMATION GUIDE

Hydrosad® XW, and Hydrosad® Toric XW (methafilcon B) Soft (Hydrophilic) Contact Lenses
**CAUTION:**
Federal Law Prohibits Dispensing Without a Prescription.

See Package Insert PI01004 for complete CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS

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INTRODUCTION:

Hydrasoft, Hydrasoft XW, Hydrasoft Toric, and Hydrasoft Toric XW Soft (Hydrophilic) Contact Lenses are made in methafilcon B with a water content of 55% by weight.

For a complete listing of available lens parameters, please refer to LENS PARAMETERS AVAILABLE below.

PRODUCT DESCRIPTION:

Hydrasoft and Hydrasoft XW (methafilcon B) soft (hydrophilic) contact lenses are available as spherical lenses. Hydrasoft Toric and Hydrasoft Toric XW (methafilcon B) Soft (Hydrophilic) contact lenses are available as astigmatic (toric) lenses. The lens material, methafilcon B, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid.

Hydrasoft contact lenses are hemispherical shells with the following dimensions:

- Diameter: 14.2mm to 15.0mm
- Base Curve: 8.0mm to 9.5mm
- Center Thickness: 0.06mm to 0.65mm (varies with power)

Spherical Lens Powers:
- Daily Wear: -20.00 to +20.00 D
- Extended Wear: -30.00 to +20.00 D

The physical/optical properties of the lens are:

- Refractive index: 1.40
- Light Transmittance: 99.6%
- Surface Character: Hydrophilic
- Water Content: 55%
- Oxygen Permeability: 19.0 x 10^-11 (cm²/sec) (ml O₂/ml x mm Hg) at 25°C

(-measured by Scheiner Versus model 920 connected to a polarographic cell)

LENS PARAMETERS AVAILABLE:

1. HYDRASOFT

- Diameter: 15.0mm
- Base Curve:
  - Standard: 8.9mm
  - Steep: 8.6mm
  - Flat: 9.2mm
- Lens Power: -20.00 to +20.00 D
- Thickness:
  - Minus: 0.09mm to 0.14mm
  - Plus: 0.10mm to 0.43mm

Optical Zone: 8.0mm to 8.5mm

2. HYDRASOFT XW

- Diameter: 15.0mm
- Base Curve:
  - Standard: 8.9mm
  - Steep: 8.6mm
  - Flat: (not available)
- Lens Power: -20.00 to +20.00 D
  - Minus: 0.06mm to 0.10mm
  - Plus: 0.10mm to 0.43mm
- Optical Zone: 8.4mm to 8.2mm

Optical Zone: 8.0mm to 8.5mm

3. HYDRASOFT TORIC AND HYDRASOFT TORIC XW

- Diameter: 15.0mm
- Base Curve:
  - Standard: 8.9mm
  - Steep: 8.6mm
  - Flat: 9.2mm
- Lens Power:
  - Spherical: -20.00 to +20.00 D
  - Cylindrical: 0.50 to 10.00
- Axis: 1° to 180°
- Optical Zone: 8.4mm

Optical Zone: 8.0mm to 8.5mm

ACTIONS:

When placed on the cornea in its hydrated state, any Hydrasoft lens referred to in this fitting guide acts as a refracting medium to focus light rays on the retina. The design of the toric lens provides a more even surface over the highly uneven astigmatic cornea and thus helps to focus light rays on the retina.

INDICATIONS:

1. Hydrasoft lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

2. Hydrasoft XW lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eye care practitioner. They are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who may exhibit astigmatism of 1.50 diopters or less that does not interfere with visual acuity.

3. Hydrasoft Toric lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and non-aphakic per-
sons with non-diseased eyes. They may be worn by persons who have astigmatism of 12.00 diopters or less.

- Hydrasoft Toric XW lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfecting as recommended by the eyecare practitioner. They are indicated for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.

Note: Only chemical disinfection may be used with the above Hydrasoft Toric lenses.

NOTE: See Package Insert for complete CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

SELECTION OF PATIENTS:

Patients chosen to wear Hydrasoft contact lenses should demonstrate proper motivation to wear lenses, a cooperative attitude, and general good health. Successful contact lens wear is dependent not only on a well fitted lens, but upon good patient communication and compliance.

FITTING PROCEDURE

* General

A pre-fitting patient history and examination are necessary to:

- determine whether a patient is a suitable candidate for contact lenses (consider patient hygiene and mental and physical state, and any pathologies which would contraindicate contact lens wear),

- make ocular measurements for initial contact lens parameter selection,

- collect and record baseline clinical information to which post-fitting examination results can be compared.

A pre-fitting examination should include a complete patient history and a thorough eye examination, including visual acuities, keratometry, and biomicroscopy.

1. Initial Lens Power Selection - Hydrasoft and Hydrasoft XW

   a. Convert the spectacle refraction to minus cylinder form.

   b. Compensate the spectacle power for vertex distance if greater than ±4.00D.

   c. If refractive astigmatism is 0.75 diopters or less, drop the cylinder and compensate for power as in step e below.

   d. If refractive astigmatism exceeds 0.75 diopters, determine equivalent sphere and then compensate for power as in step e below.

   e. Add +0.25 diopters to compensate for minus tear lens.

2. Initial Lens Power Selection - Hydrasoft Toric and Hydrasoft Toric XW

   a. Convert the spectacle refraction to minus cylinder form.

   b. Compensate the spherical power for vertex distance if greater than ±4.00D.

   c. For MINUS lenses, determine the power in this manner:

   1. For cylinders between -1.00 and -2.00
      - add +0.25 to sphere power
      - add +0.25 to cylinder power

   2. For cylinders between -2.25 and -3.50
      - add +0.50 to sphere power
      - add +0.50 to cylinder power

   3. For cylinders between -3.75 and -5.75
      - add +0.75 to sphere power
      - add +0.75 to cylinder power

   4. For cylinders between -6.00 and -10.00
      - add +1.00 to sphere power
      - add +1.00 to cylinder power

   d. For PLUS lenses, determine the power in this manner:

   1. Leave the cylinder power unchanged

   2. For cylinders between -1.00 and -2.00
      - add +0.50 to sphere power

   3. For cylinders between -2.25 and -3.50
      - add +0.75 to sphere power

   4. For cylinders between -3.75 and -5.75
      - add +1.00 to sphere power

   5. For cylinders between -6.00 and -10.00
      - add +1.25 to sphere power

NOTE: When the sphere power is within one-half diopter of plano, reduce the recommended addition of plus by 50%.

   e. For both plus and minus lenses, the lens axis should be the same as the refractive axis.

   1. For cylinder powers of 2.00 diopters or less, the axis tolerance may be ±5°

   2. For cylinder powers greater than 2.00 diopters, the axis tolerance should be ±3°.
Examples:

- Refraction: -2.00 -1.50 x 180
  Spherical power: add +0.25 to refractive spherical power
  Cylinder power: add +0.25 to refractive cylinder power
  Cylinder axis: 180°
  Initial lens to try: -1.75 -1.25 x 180

- Refraction: -5.00 -3.00 x 30
  Spherical power: add +0.25 for vertex distance
  Cylinder power: add +0.50 to refractive cylinder power
  Cylinder axis: 90°
  Initial lens to try: -4.25 -2.50 x 90

- Refraction: -3.00 -5.00 x 170
  Spherical power: add +1.00 to refractive spherical power
  Cylinder power: same as refractive cylinder power
  Cylinder axis: 170°
  Initial lens to try: +4.00 -5.00 x 170

Note: It is preferable to be slightly under corrected on the cylinder power.

3. Initial Lens Diameter Selection

The majority of patients can be successfully fit with the 15.0 diameter. If you experience difficulty, please call the CooperVision consultation department.

4. Initial Lens Base Curve Selection

With any Hydrasoft lens, usually the only variable parameter is the power. Therefore, as long as the flattest corneal curvature is no flatter than 41.00 diopters and no steeper than 45.00 diopters and the corneal diameter is average, the standard 8.9mm base curve lens will fit adequately. (The standard 14.2mm diameter, 8.6mm base curve is equivalent.)

Due to differences in corneal diameter and the rate of corneal flattening, this single base curve may fit differently on corneas having the same measured radius of curvature. The draping effect of the lens will compensate for much of this corneal variation. Diagnostic lens sets are available to help evaluate base curve/cornea relationships and patient response to the lenses.

5. Initial Lens Evaluation

a. Remove the lens from the vial and rinse it with a recommended sterile rinsing solution before placing it on the patient's eye.

b. Allow approximately 20 minutes for the lenses to equilibrate on the eye.

c. Check the lens positioning and movement with a slit lamp. The lens should be stable with the laser mark oriented in the 6 o'clock position. There should be complete corneal coverage with 0.5 to 1.0mm post-blinking movement in primary gaze.

d. Assess visual acuity. When the proper physical fit has been achieved, perform a sphero-cylinder over-refraction if necessary to determine best visual acuity. The new lens power can be calculated by entering the parameters into the pocket computer, or call CooperVision Customer Service for assistance.

Note: Check visual acuity on two different occasions before deciding to make power changes of ±0.50 diopters or less.

e. If the physical fit and visual acuity are acceptable, allow the patient to wear the lens for one week.

6. Follow-up Care

a. Follow-up examinations, as recommended by the eyecare practitioner, are necessary to ensure continued successful contact lens wear.

b. Barring complications, the minimum schedule of follow-up examinations should be:

   1. DAILY WEAR - Hydrasoft and Hydrasoft Toric
      a. One week from the start of lens wear.
      b. One month from the start of lens wear.
      c. Three months from the start of lens wear.
      d. Every six months thereafter.

   2. EXTENDED WEAR - Hydrasoft XW and
      Hydrasoft Toric XW
      a. Twenty-four hours from the start of extended wear, as soon as possible after the patient awakens.
      b. One week from the start of extended wear.
      c. One month from the start of extended wear.
      d. Three months from the start of extended wear.*

*NOTE: Extended wear patients require frequent and careful monitoring of lenses and ocular health to minimize complications.

c. Prior to a follow-up examination, the contact lenses should be worn for at least six continuous hours and the patient should be asked to identify any problems which might be occurring related to contact lens wear.

d. Review proper lens care and handling instructions and wearing schedule.
e. With the lenses in place on the eyes, evaluate fitting performance to assure that CRITERIA OF A WELL FITTED LENS continue to be satisfied. (See Section entitled CLINICAL ASSESSMENT). Examine the lenses closely for surface deposition and/or damage. Replace lenses if deposits develop which cannot be removed.

f. After lens removal, conduct a thorough biomicroscopy examination.

1. The presence of vertical corneal striae in the posterior central cornea and/or neovascularization is indicative of excessive corneal edema.

2. The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of an unclean lens, a reaction to solution preservatives, excessive lens wear, and/or a poorly fitting (tight) lens.

3. Papillary conjunctival changes may be indicative of an unclean and/or damaged lens.

g. Compare best corrected visual acuity and keratometry readings to the baseline findings. Excessive changes from baseline are indicative of corneal edema and/or a poorly fitting lens.

If any of the above observations are judged abnormal, various professional judgments are necessary to alleviate the problem and restore the eye to optimal conditions. If the CRITERIA OF A WELL FITTED LENS are not satisfied during any follow-up examination, the patient should be re-fitted with a more appropriate lens.

IN OFFICE CARE OF TRIAL LENSES:

Eyecare practitioners should educate contact lens technicians concerned proper care of trial lenses.

Each contact lens is shipped sterile in a glass vial with sterile buffered isotonic saline. Hands should be thoroughly washed and rinsed and dried with a lint free towel prior to handling a lens. In order to insure sterility, the vial should not be opened until immediately prior to use.

Prior to reusing in a diagnostic procedure or before dispensing to a patient, lenses MUST be surface cleaned and disinfected. Diagnostic lenses may be disinfected by chemical (not heat) disinfection systems. To ensure adequate disinfection, follow the instructions accompanying the disinfecting solution. DO NOT alter, dilute or mix disinfection systems.

If lenses are not to be used immediately following disinfection, leave them in the closed/unopened case. Refer to the solution instructions for information on storage of lenses.

RECOMMENDED INITIAL WEARING SCHEDULE:

Although many practitioners have developed their own wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to carefully follow the wearing schedule recommended by the eyecare practitioner regardless of how comfortable the lenses feel.

DAILY WEAR: (less than 24 hours, while awake). Hydrasoft and Hydrasoft Toric lenses are suitable for daily wear. The maximum suggested wearing time is:

<table>
<thead>
<tr>
<th>Day</th>
<th>Hours</th>
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<tr>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
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<tr>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>All Waking Hours</td>
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Adherence to a gradual increase in wearing time is very important. Some flexibility as necessitated by the patient's daily routine is permissible after the first 6 days of wear. The suggested wearing time may be broken into two periods, separated by a one or two hour rest period of no lens wear.

EXTENDED WEAR: (greater than 24 hours, including while asleep). Hydrasoft XW and Hydrasoft Toric XW lenses are suitable for extended wear. The wearing time should be determined by the eye care practitioner. First time wearers of contact lenses should begin by following the DAILY WEAR SCHEDULE above.

NOTE: First time wearers of contact lenses should have an adaptation period of at least 6 days of daily wear before starting extended wear. Previous wearers may begin extended wear immediately if so directed by the eye care practitioner. It is important to examine the patient as soon as possible after the first 24 hour period of extended wear.

CLINICAL ASSESSMENT:

1. Criteria of a Well-Fitted Lens

a. The lens centers easily after a blink and provides complete corneal coverage.

b. In primary gaze, there is slight post-blinking movement (0.5 to 1.0mm). On upward gaze, the lens
sags approximately 1 to 2mm.

c. Keratometry: Mire quality is clear and constant over the lens surface.

d. Retinoscopy: The reflex through the lens is clear and indistinguishable from the reflex without a lens in place.

e. Over-refraction: Good end-point acuity that is not compromised prior to or following a blink.

f. There is no impingement of the lens edge on the sclera.

2. Characteristics of a Tight (Steep) Lens

a. The lens does not move freely. There is impingement of the lens edge on the sclera, seen either as scleral indentation or as blanching of the scleral blood vessels.

b. Bubbles under the lens.

c. Keratometry: Distorted or blurred mires preceding or following a blink.

d. Poor or variable vision. Vision clears momentarily immediately after each blink, but is blurred in between blinks.

e. Over-refraction: Unable to achieve good end-point acuity. If good visual acuity cannot be obtained through the lens with the spherocylindrical over-refraction and axis realignment, re-evaluation of the physical fit should be considered.

3. Characteristics of a Loose (Flat) Lens

a. Excessive lens movement (more than 1mm after blinking in primary gaze).

b. Poor or variable vision. Vision is clear between blinks, but blurs after each blink.

c. Over-refraction: Unable to achieve good end-point acuity. If good visual acuity cannot be obtained through the lens with the spherocylindrical over-refraction and axis realignment, re-evaluation of the physical fit should be considered.

MONOVISION FITTING GUIDELINES:

2. EYE SELECTION

Generally, the non-dominant eye is corrected for near vision. The following test for eye dominance can be used:

a. Ocular Preference Determination Methods

Method 1 - Determine which eye is the "sight eye". Have the patient point to an object at the far end of the room. Cover one eye. If the patient is still pointing directly at the object, the eye being used is the dominant (sighting) eye.

Method 2 - Determine which eye will accept the added power with the least reduction in vision. Place a trial spectacle near add lens in front of one eye and then the other while the distance refractive error correction is in place for both eyes.
Determine whether the patient functions best with the near add lens over the right or left eye.

b. **Refractive Error Method**

For anisometropic corrections it is generally best to fit the more hyperopic (less myopic) eye for distance and the more myopic (less hyperopic) eye for near.

c. **Visual Demands Method**

Consider the patient's occupation during the eye selection process to determine the critical vision requirements. If a patient's gaze for near tasks is usually in one direction, correct the eye on that side for near.

Example: A secretary who places copy to the left side of the desk will usually function best with the near lens on the left eye.

3. **SPECIAL FITTING CONSIDERATIONS**

**Unilateral Lens Correction**

There are circumstances where only one contact lens is required. As an example, an emmetropic presbyopic patient would only require a near lens while a bilateral myope may require only a distance lens.

Examples:

A presbyopic emmetropic patient who requires a +1.75 diopter add would have a +1.75 lens on the near eye and the other eye left without a lens.

A presbyopic patient requiring +1.50 diopter add who is -2.50 diopters myopic in the right eye and -1.50 diopters myopic in the left eye may have the right eye corrected for distance and the left uncorrected for near.

4. **NEAR ADD DETERMINATION**

Always prescribe the lens power for the near eye that provides optimal near acuity at the midpoint of the patient's habitual reading distance. However, when more than one power provides optimal reading performance, prescribe the least plus (most minus) of the powers.

5. **TRIAL LENS FITTING**

A trial fitting is performed in the office to allow the patient to experience monovision correction. Lenses are fit according to the directions in the general fitting procedures described earlier in this guide.

Case history and standard clinical evaluation proce-

- dures should be used to determine the prognosis. Determine which eye is to be corrected for distance and which eye is to be corrected for near. Next determine the near add. With trial lenses of the proper power in place observe the reaction to this mode of correction.

Immediately after the correct power lenses are in place, walk across the room and have the patient look at you. Assess the patient's reaction to distance vision under these circumstances. Then have the patient look at familiar near objects such as a watch face or fingernails. Again assess the reaction. As the patient continues to look around the room at both near and distant objects, observe the reactions. Only after these vision tasks are completed should the patient be asked to read print. Evaluate the patient's reaction to large print (e.g., typewritten copy) at first and then graduate to newsprint and finally smaller type sizes.

After the patient's performance under the above conditions are completed, tests of visual acuity and reading ability under conditions of moderately dim illumination should be attempted.

An initial unfavorable response in the office, while indicative of a guarded prognosis, should not immediately rule out a more extensive trial under the usual conditions in which a patient functions.

6. **ADAPTATION**

Visually demanding situations should be avoided during the initial wearing period. A patient may at first experience some mild blurred vision, dizziness, headaches, and a feeling of slight imbalance. You should explain the adaptational symptoms to the patient. These symptoms may last for a brief minute or for several weeks. The longer these symptoms persist, the poorer the prognosis for successful adaptation.

To help in the adaptation process the patient can be advised to first use the lenses in a comfortable familiar environment such as in the home.

Some patients feel that automobile driving performance may not be optimal during the adaptation process. This is particularly true when driving at night. Before driving a motor vehicle, it may be recommended that the patient be a passenger first to make sure that their vision is satisfactory for operating an automobile. During the first several weeks of wear (when adaptation is occurring), it may be advisable for the patient to only drive during optimal driving conditions. After adaptation and success with these activities, the patient should be able to drive under other conditions with caution.
7. OTHER SUGGESTIONS

The success of the monovision technique may be further improved by having your patient follow the suggestions below:

• Having a third contact lens (distance power) to use when critical distance viewing is needed.
• Having a third contact lens (near power) to use when critical near viewing is needed.
• Having supplemental spectacles to wear over the monovision contact lenses for specific visual tasks may improve the success of monovision correction. These "asymmetric power" spectacles may be for balanced near or far vision. This is particularly applicable for those patients who cannot meet state drivers licensing requirements with a monovision correction.
• Make use of proper illumination when carrying out visual tasks.

Success in fitting monovision can be improved by the following suggestions:

• Reverse the distance and near eyes if a patient is having trouble adapting.
• Refine the lens powers if there is trouble with adaptation. Accurate lens power is critical for presbyopic patients.
• Emphasize the benefits of the clear near vision in straight ahead and upward gaze with monovision.

The decision to fit a patient with a monovision correction is most appropriately left to the eye-care practitioner in conjunction with the patient after carefully considering the patient's needs.

• All patients should be supplied with a copy of the Patient Instructions.

PATIENT LENS CARE DIRECTIONS:

Refer to the Package Insert for complete lens care directions in the following sections:

• LENS CARE DIRECTIONS
• Chemical Lens Disinfection (Including Hydrogen Peroxide)
• LENS DEPOSITS AND USE OF ENZYMATIC CLEANING PROCEDURE
• LENS CASE CLEANING AND MAINTENANCE
• CARE FOR A DRIED OUT (DEHYDRATED) LENS
• CARE FOR A STICKING (NONMOVING) LENS

REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing any Hydrasoft contact lens or experienced with the lenses should be reported to:

CooperVision
711 North Road
Scottsville, New York 14546
(800) 341-2020
www.coopervision.com

HOW SUPPLIED:

Each lens is supplied sterile in a glass vial containing sterile buffered isotonic saline solution. The glass vial is labeled with the base curve, diameter, dioptic power (cylinder and axis are included for a toric lens), manufacturing lot number, and expiration date of the lens. The vial label for a toric lens also gives the cylinder power and axis.

Part number: PFG01006
Revision A
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