

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628

Indications

The OPTIMUM GP (rofluvocon A) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The OPTIMUM GP (rofluvocon A) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The OPTIMUM GP (rofluvocon A) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The OPTIMUM GP (rofluvocon A) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons.

The OPTIMUM GP (rofluvocon A) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of **irregular corneal conditions** such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628, K161100

Indications

The OPTIMUM GP (rofluvocon C) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The OPTIMUM GP (rofluvocon C) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The OPTIMUM GP (rofluvocon C) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The OPTIMUM GP (rofluvocon C) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons.

The OPTIMUM GP (rofluvocon C) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of **irregular corneal conditions** such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628, K161100, K160859, K180616

Indications

The OPTIMUM GP (rofluvocon D) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The OPTIMUM GP (rofluvocon D) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The OPTIMUM GP (rofluvocon D) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The OPTIMUM GP (rofluvocon D) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons.

The OPTIMUM GP (rofluvocon D) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of **irregular corneal conditions** such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The OPTIMUM GP OK contact lenses are indicated for **daily wear in an orthokeratology fitting program** for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. OPTIMUM GP (rofluvocon D) Daily Wear Contact Lenses are indicated for **therapeutic use for the management of irregular and distorted corneal surfaces** where the subject:

1. Cannot be adequately corrected with spectacle lenses.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628, K161100, K160859, K180616

2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

OPTIMUM GP (rofluocon D) Daily Wear Contact Lenses are also **indicated for therapeutic use in eyes with ocular surface disease** (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the OPTIMUM GP (rofluocon D) Daily Wear Contact Lenses may concurrently provide correction of refractive error.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628, K161100, K160859, K180616

Indications

The OPTIMUM GP (rofluvocon E) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The OPTIMUM GP (rofluvocon E) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The OPTIMUM GP (rofluvocon E) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The OPTIMUM GP (rofluvocon E) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons.

The OPTIMUM GP (rofluvocon E) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of **irregular corneal conditions** such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The OPTIMUM GP OK contact lenses are indicated for **daily wear in an orthokeratology fitting program** for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. OPTIMUM GP (rofluvocon E) Daily Wear Contact Lenses are indicated for **therapeutic use for the management of irregular and distorted corneal surfaces** where the subject:

1. Cannot be adequately corrected with spectacle lenses.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials



510k(s): K033594, K062548, K070628, K161100, K160859, K180616

2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

OPTIMUM GP (rofluocon E) Daily Wear Contact Lenses are also **indicated for therapeutic use in eyes with ocular surface disease** e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the OPTIMUM GP (rofluocon E) Daily Wear Contact Lenses may concurrently provide correction of refractive error.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials



510k(s): K182304

Indications

The Hyper GP (tisilfocon A) **SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The Hyper GP (tisilfocon A) **TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The Hyper GP (tisilfocon A) **MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Hyper GP (tisilfocon A) **IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The Hyper GP (tisilfocon A) **ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials

HEXA100

510k(s): K171077, K180616

Indications

The HEXA100 (hexafocon A) **SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The HEXA100 (hexafocon A) **TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

The HEXA100 (hexafocon A) **MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The HEXA100 (hexafocon A) **IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The HEXA100 (hexafocon A) **ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated for **therapeutic use for the management of irregular and distorted corneal surfaces** where the subject:

1. Cannot be adequately corrected with spectacle lenses.
2. Requires a rigid gas permeable contact lens surface to improve vision.
3. Is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Notes

Optional Plasma Treatment, Tangible® Hydra-PEG®*

510k Material Indications

GP Materials

HEXA100

510k(s): K171077, K180616

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

HEXA100 (hexafocon A) Daily Wear Contact Lenses are also **indicated for therapeutic use in eyes with ocular surface disease** (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the HEXA100 (hexafocon A) Daily Wear Contact Lenses may concurrently provide correction of refractive error.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Notes

Optional Plasma Treatment, Tangible[®] Hydra-PEG^{®*}