

Neo Spectra™ ST

Universal Composite Restorative

Neo Spectra™ ST Effects

Universal Composite Restorative

CAUTION: For dental use only.

USA: Rx only.

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1 Product description

Neo Spectra™ ST and **Neo Spectra™ ST Effects** are nano-ceramic, light cured, radiopaque, universal composites based on the novel **SphereTEC® filler technology** indicated for both, direct and indirect restorations.

The spherical, granulated filler technology called SphereTEC® leads to a ball-bearing effect that takes the handling properties of Neo Spectra™ ST and Neo Spectra™ ST Effects to the next level:

- **Neo Spectra™ ST and Neo Spectra™ ST Effects easily adapt to cavity surfaces but does not stick to hand instruments.**
- **Neo Spectra™ ST and Neo Spectra™ ST Effects are easy to sculpt precisely and have a high slump resistance.**
- **Neo Spectra™ ST and Neo Spectra™ ST Effects provide a firm consistency but are at the same time easy to extrude from Compules® Tips.**

Neo Spectra™ ST comprises of five universal CLOUD shades of intermediate translucency named (A1) to (A4).

Each universal CLOUD shade is designed to achieve shade match with a range of VITA®¹ shades. As a whole, the five universal CLOUD shades cover all 16 VITA® classic shades and allow for aesthetic clinical results. Additionally, one bleach shade (BW) is available for bleached teeth. Neo Spectra™ ST Effects offers 2 opaque dentin shades (D1 and D3) and 1 translucent enamel shade (E1) that work with the Neo Spectra™ ST and Neo Spectra™ ST Effects universal CLOUD shades in a simplified layering system to provide added opacity and/or translucency as needed in esthetically demanding cases.

¹ Not a registered trademark of Dentsply Sirona, Inc.

The spherical, granulated fillers consisting of submicron primary glass fillers, provide a fast and easy polishing procedure resulting in an outstanding gloss.

1.1 Indications

- Direct restorations of all cavity classes in anterior and posterior teeth.
- Indirect fabrication of inlays, onlays and veneers.

1.2 Contraindications

- Use with patients who have a history of severe allergic reaction to methacrylate resins or any of the other components.

1.3 Delivery forms

Neo Spectra™ ST Universal Composite Restorative is available as HV (High Viscosity) and LV (Low Viscosity) viscosities for preferred handling. Neo Spectra™ ST Effects is available as HV (High Viscosity) only. Both Neo Spectra™ ST and Neo Spectra™ ST Effects offer two delivery options:

- Predosed Compules® Tips
- Syringes (except BW shade)

1.4 Composition

- Methacrylate modified polysiloxane (organically modified ceramic)
- Dimethacrylate resins
- Fluorescent pigment
- UV stabilizer
- Stabilizer
- Camphorquinone
- Ethyl-4(dimethylamino)benzoate
- Bis-(4-methyl-phenyl)iodonium hexafluorophosphate
- Barium-aluminum-borosilicate glass
- Ytterbium fluoride
- Iron oxide pigments and titanium oxide pigments according to shade

Filler system based on SphereTEC®.

The filler system comprises barium glass, prepolymerized filler and ytterbium fluoride:
HV: 78-80 weight-% or 60-62 volume-%.

LV: 76-78 weight-% or 57-60 volume-%.

Additional ingredients are catalysts, additives, stabilizers and pigments (~1 weight-%, according to shade).

The total amount of inorganic fillers is:

HV: 72-74 weight-% or 50-52 volume-%.

LV: 71-72 weight-% or 48-50 volume-%.

The particle size of the inorganic fillers ranges from 0.1 to 3.0 μm .



1.5 Compatible adhesives

The material is to be used in combination with a (meth)acrylate-based dentin/enamel adhesive such as the Dentsply Sirona Prime&Bond and Xeno range of adhesives.

2 Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Directions for Use.



Safety alert symbol.

- This is the safety alert symbol. It is used to alert you to potential personal injury hazards.
- Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

The material contains methacrylates and polymerizable monomers which may be irritating to skin, eyes and oral mucosa and may cause sensitization by skin contact and allergic contact dermatitis in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. In case of contact, red-dish rashes may be seen on the skin. If contact with skin occurs, remove material with cotton and alcohol and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid contact with oral soft tissues/mucosa** to prevent inflammation. If accidental contact occurs, remove material from the tissues. Flush mucosa with plenty of water and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

2.2 Precautions

This product is intended to be used only as specifically outlined in these Directions for Use.

Any use of this product inconsistent with these Directions for Use is at the discretion and sole responsibility of the dental practitioner.

- If refrigerated, allow material to reach room temperature prior to use.
- Contact with saliva, blood and sulcus fluid during application may cause failure of the restoration. Use adequate isolation such as rubber dam.
- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- The syringes cannot be reprocessed. To prevent syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Discard syringes if contaminated.
- As additional precautionary measure, syringes may be protected from gross debris but not from all contamination by applying a protective barrier.
- Use of Compules® Tips with the Compules® Tips Gun is recommended.
- The Compules® Tips Gun is only intended to be used with Dentsply Sirona Compules® or Compula® Tips.
- For further information please refer to the Compules® Tips Gun Directions for Use.
- The shade guide and the individual shade guide tabs cannot be reprocessed. To prevent the shade guide and the individual shade guide tabs from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide and the individual shade guide tabs are handled with clean/disinfected gloves.
- The material should extrude easily. DO NOT USE EXCESSIVE FORCE. Excessive pressure may cause the Compules® Tip to rupture or to eject from the Compules® Tips Gun.
- Tightly close syringes immediately after use.
- Interactions:
 - Do not use eugenol- or hydrogen peroxide-containing materials in conjunction with this product since they may interfere with hardening of the product.

2.3 Adverse reactions

- Eye contact: Irritation and possible corneal damage.
- Skin contact: Irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Contact with mucous membranes: Inflammation (see Warnings).

2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store at temperatures between 2 °C and 28 °C (36 °F and 82 °F).
- Keep out of direct sunlight and protect from moisture.
- Do not freeze.
- Do not use after expiration date.

3 Step-by-step instructions

3.1 Shade selection

1. Prior to shade selection, clean the tooth surface with prophylaxis paste to remove plaque or surface stain.
2. Select the shade while teeth are hydrated.

Neo Spectra™ ST restorative has been scientifically designed to allow the tooth structure enamel and dentin to blend together with the composite with a life-like translucent result. The 5 A shades of Neo Spectra™ ST restorative adequately reproduce the traditional 16 VITA® shades.

For esthetically demanding cases requiring special effects to achieve the desired esthetic result, Neo Spectra™ ST Effects offers 2 dentin shades and 1 enamel shade that work with the Neo Spectra™ ST universal CLOUD shades in a simplified layering system to provide added opacity and/or translucency as needed.

For shade selection, there are two tools that may be used:

- The Neo Spectra™ ST and Neo Spectra™ ST Effects shade guide. The Neo Spectra™ ST and Neo Spectra™ ST Effects shade guide consists of tabs, which are manufactured from composite with optical properties close to those of Neo Spectra™ ST and Neo Spectra™ ST Effects.
- The VITA® classical shade guide in combination with the i-shade label. The Neo Spectra™ ST and Neo Spectra™ ST Effects i-shade label facilitates shade selection by assigning one of the five universal CLOUD shades to each of the 16 VITA® shades.

3.1.1 Shade selection with the Neo Spectra™ ST and Neo Spectra™ ST Effects shade guide

1. Use the shade tabs of the Neo Spectra™ ST and Neo Spectra™ ST Effects shade guide to select the shade closest to the shade of the area to be restored.

Avoid contamination of the shade guide.



To prevent the shade guide from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide is handled offside the dental unit with clean/disinfected gloves. For shade selection, remove individual tabs from shade guide holder.

3.1.2 Shade selection with VITA® classical shade guide and i-shade label



Have the i-shade label ready.

To make sure that the i-shade label is available chairside, we recommend sticking it on the rear side of the VITA® classical shade guide.

1. Select the VITA® classical reference tooth, the central part of which best matches the area of the tooth to be restored.
2. Use the i-shade label (see table below) to identify the matching Neo Spectra™ ST universal CLOUD shade, and appropriate Neo Spectra™ ST Effect shade(s) if enhanced esthetic effects are desired.

Tooth shade according to the VITA® Classical Shade Guide	A1	B1	C1	A2	B2	D2	A3	C2	D3	D4	A3.5	B3	B4	C3	A4	C4		
Recommended Neo Spectra™ ST universal CLOUD shade	A1		A2		A3			A3.5				A4						
Recommended Neo Spectra™ ST Effects shades	D1				D3				E1									

3.2 Cavity preparation

1. Clean the tooth surface with a fluoride free prophylaxis paste (e.g. Nupro® prophylaxis paste).
2. Prepare cavity (unless not necessary, e.g. cervical lesion).
3. Use adequate isolation such as rubber dam.
4. Rinse surface with water spray and carefully remove rinsing water. Do not desiccate the tooth structure.

3.2.1 Matrix placement and wedging (Class II restorations)

1. Place a matrix (e.g. AutoMatrix® or Palodent® Matrix System) and wedge. Burnishing of the matrix band will improve contact and contour. Pre-wedging or BiTine® ring placement is recommended.

3.3 Pulp protection, tooth conditioning/dentin pre-treatment, adhesive application

Refer to adhesive manufacturer's Directions for Use for pulp protection, tooth conditioning and/or adhesive application. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately to placement of the material.

3.4 Application

Apply material in increments immediately after the application of the adhesive. The material is designed to be cured in increments up to a 2 mm depth/thickness.

Using Compules® Tips

1. Insert Compules® Tip into the notched opening of the Compules® Tips Gun. Be certain that the collar on the Compules® Tip is inserted first.
2. Remove the colored cap from the Compules® Tip. The Compules® Tip may be rotated 360° to gain the proper angle of entrance into the cavity or to the mixing pad.
DO NOT USE EXCESSIVE FORCE.
Indirect use: Dispense the necessary amount of material onto a mixing pad and protect against light. Apply material into the cavity with a plastic instrument.
- or -

Direct intraoral use: Dispense the material directly into the cavity preparation using a slow, steady pressure.

3. To remove the used Compules® Tip, be sure that the Compules® Tips Gun plunger is pulled back completely by allowing the handle to open to its widest position. Apply a downward motion to the front end of the Compules® Tip and remove.

Excessive force.



Injury.

1. Apply slow and steady pressure on the Compules® Tips Gun.
2. Do not use excessive force. Compules® Tip rupture or ejection from Compules® Tips Gun may result.

Using syringes



Avoid contamination of the syringe.

To prevent the syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled offsite the dental unit with clean/disinfected gloves.

1. Remove the cap.
2. Turn the handle of the syringe slowly in a clockwise direction and dispense the necessary amount of the material onto a mixing pad.
3. Point the front tip of the syringe upwards and turn the handle anti-clockwise to prevent oozing of the material.
4. Immediately close the syringe with the cap.
5. Protect the restorative material on the mixing pad against light.

3.4.1 Applying restorative

1. Fill the whole cavity incrementally. Each layer \leq 2 mm.
2. Cure each layer according to the table below [3.5 Light curing].

Technique Tips:

- **Use a single opacity for most common cases:** Because the Neo Spectra™ ST universal CLOUD shades are designed to replace both dentin and enamel, a single universal CLOUD shade is sufficient for most restorations. If esthetic blending of more than one universal CLOUD shade is desired, shade layers may be individually cured to form a foundation for subsequent shade placement.
- **Use multiple opacities for esthetically demanding cases:** For esthetically demanding cases such as a large Class IV or a through-and-through Class III, Neo Spectra™ ST Effects dentin and enamel shades can be used with Neo Spectra™ ST universal CLOUD shades in a simplified layering system to provide added opacity and/or translucency.
 - Restore the palatal half of the tooth with the dentin shade². Leave room for the universal CLOUD shade at the incisal edge.
 - Place the universal CLOUD shade along the incisal edge and cure the completed palatal layer.
 - Restore the facial half of the tooth with the universal CLOUD shade². If increased translucency along the incisal edge is desired, place the enamel shade there, then cure the completed facial layer.

² Light curing of individual increments required when layer thickness reaches 2 mm.

3.5 Light curing

1. Light cure each increment with a suitable curing light³. Cure universal A shades, BW, and E1 increments for 10 seconds, and D1 and D3 shades for 30 seconds when using a curing light that has a minimum irradiance of 800 mW/cm².
Cure universal A shades, and BW for 20 seconds, E1 for 10 seconds, and D1 and D3 shades for 40 seconds when minimum irradiance is between 550 mW/cm² and 800 mW/cm².
Refer to curing light manufacturer's Directions for Use for compatibility and curing recommendations.

Curing time for 2 mm increments

Neo Spectra™ ST and Neo Spectra™ ST Effects Curing Recommendations		
Shades	Output mW/cm ²	Curing Time
A1-A4, BW	≥ 550	20 seconds
	≥ 800	10 seconds
D1, D3	≥ 550	40 seconds
	≥ 800	30 seconds
E1	≥ 550	10 seconds



Curing time table.

The curing time table above also appears on all outer packages.



Insufficient curing.

Inadequate polymerization.

1. Check compatibility of curing light.
2. Check curing cycle.
3. Check minimum irradiance.
4. Cure each area of each increment for the recommended curing time.
5. Check distance to surface to be cured.

3.6 Finishing and polishing

1. Contour the restoration using finishing burs or diamonds.
2. Use Enhance® finishing devices for additional finishing.
3. Prior to polishing, check that surface is smooth and free of defects.
4. For achieving a very high luster of the restoration, we recommend Enhance® and Enhance® PoGo®, finishing and polishing instruments, Prisma® Gloss™ Regular and Extrafine polishing paste.

For contouring, finishing, and/or polishing, follow the manufacturer's Directions for Use.

³ Curing light designed to cure materials containing camphorquinone (CQ) initiator. Peak of spectrum in the range of 440-480 nm.

4 Hygiene

Cross-contamination.

Infection.



- Do not reuse single use products. Dispose of in accordance with local regulations.
- Syringes cannot be reprocessed. Dispose of contaminated syringes in accordance with local regulations.
- Reprocess reusable products according to the instructions.

4.1 Compules® Tips Gun

For reprocessing instructions please refer to the Directions for Use of the Compules® Tips Gun, which is available on our webpage at www.dentsplysirona.com and www.dentsply.eu/IFU. If requested, we will send you a free printed copy of the Directions for Use in the language you require within 7 days. You can use the order form provided on www.dentsply.eu/IFU for this purpose.

4.2 Compules® Tips – cross-contamination

Cross-contamination.

Infection.



- Do not reuse Compules® Tips. Dispose of Compules® Tips in accordance with local regulations.

4.3 Syringes – cross-contamination

Cross-contamination.

Infection.



- The syringes cannot be reprocessed.
- To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Do not reuse syringes if contaminated.
- Dispose contaminated syringes in accordance with local regulations.

To prevent syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended. The use of protective barriers is an additional precautionary measure against gross debris but not against all contamination.

Incidental contact of the syringe with water, soap or a water-based hospital-level disinfection solution will not damage syringe body. Do not allow any solution contact with contained material. Discard composite material that has been in contact with any fluid or non-sterile instrument.

Dry the syringe with a lint-free single use cloth. Wipe syringe gently.

4.4 Shade guide and individual shade guide tabs – cross-contamination

Cross-contamination.

Infection.

- The shade guide and the individual shade guide tabs cannot be reprocessed.
- To prevent the shade guide and the individual shade guide tabs from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the shade guide and the individual shade guide tabs are handled with clean/disinfected gloves. Do not reuse shade guide and the individual shade guide tabs if contaminated.
- Dispose contaminated shade guide and the individual shade guide tabs in accordance with local regulations.



5 Lot number () , expiration date () and disposal

1. Do not use after expiration date.
ISO standard is used: "YYYY-MM" or "YYYY-MM-DD".
2. The following numbers should be quoted in all correspondence:
 - Reorder number
 - Lot number
 - Expiration date
3. Dispose in accordance with local regulations.

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[These Directions for Use are based on Master Version 01]