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Instructions For Use Non-Swivel Highspeed Handpiece

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Technical Specifications

Drive air pressure: 220 to 280 kPa (32 to 40 psi) Recommended: 220 kPa (32 psi) Air Consumption: 42 to 55 NL/min (1.1 to 1.9 cfm) Free speed: 480,000 rpm (557) & 375,000 rpm (757) Burs: Recommended length 19mm Range 16-21mm (557) & 19-25mm (757)

Burs less than 16mm NOT RECOMMENDED

Shank diameter: 1.59mm to 1.60mm per ISO and ADA standards

Shaft clamping length: 11mm

Working diameter: maximum 2mm (0.080 inches) Recommended cutting force: 2 to 3 N (0.45 to 0.68 lbs)

Fixed back connection: ISO 9168 type 2 (Midwest 4-hole) coupling

Model Reference

ii

557/757 ProStyle SF Lite L,C

REF

13001-0XX, 13004-0XX, 13621-0XX, 13624-0XX

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1 Product Description

HighSpeed dental air driven Handpiece, 4-Hole connection, Push Button bur changing.

1.1 Purpose – Proper use

Purpose:

This highspeed handpiece is

- Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous.
- A medical device according to relevant national statutory regulations. Indications for use:
- The Lares Research 557 and 757 highspeed handpieces are intended to be used by licensed dental professionals to reduce hard tooth structure, carry out cavity

preparations and perform restorative dentistry.

Proper use:

According to these regulations, this handpiece may only be used for the described application by a knowledgeable user. The following must be observed:

- The applicable health and safety regulations,
- The applicable accident prevention regulations,
- These instructions for use.

According to these regulations, it is the responsibility of the user to:

- Only use equipment that is operating correctly,
- Use the equipment for the proper purpose,
- Protect him or herself, the patient and third parties from danger, and
- Avoid contamination from the product.

For professional use only.

This product is intended for use only by licensed dental professionals. Before operating handpiece, carefully read and follow these instructions.

• Observe all cautions and warnings during use.

3

2 Introduction

Dear User,

Congratulations on purchasing this Lares Research quality handpiece. You are now the owner of the most advanced highspeed handpiece available. By following these instructions you will be able to work smoothly, economically and safely.

SYMBOLS

Refer to the Chapter on Safety/Warning symbol.	\triangle
Important information for users and service technicians	
Action request	
Can be sterilized with steam up to 135 °C (275 °F)	134 °C

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.

$\boldsymbol{\wedge}$	
<u> </u>	CAUTION United States federal law restricts this device to sale by or on the order of a dentist. (21 CFR 801.109)
$\underline{\land}$	For professional use only. This product is intended for use only by licensed dental professionals. Before operating handpiece, carefully read and follow these instructions. ▶ Observe all cautions and warnings during use.

3 Safety

3.1 Description of safety instructions

WARNING SYMBOL

Structure

▲ DANGER

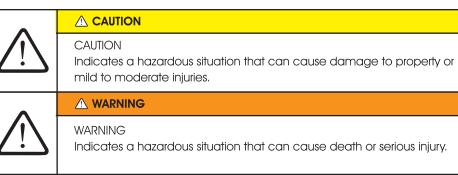
The introduction describes the type and source of the hazard. This section describes the potential consequences of non-observance.

▶ The optional step includes necessary measures for hazard prevention.

Description of hazard levels

The safety instructions listed here, together with the three levels of danger, will help avert damage and injury.

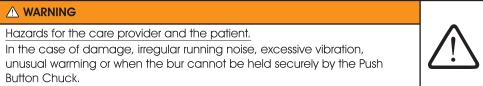




▲ DANGER

DANGER Indicates a hazardous situation that can directly cause death or serious injury.

3.2 Safety instructions



Do not use further and have handpiece serviced.

Hazard from contraindication.



If the soft tissue in the oral cavity is injured, the compressed air may enable septic substances to enter the tissue. Using the handpiece in the presence of an open wound may result in subcutaneous emphysema and accompanying serious patient health hazards, including permanent disability or death.

Treatment must be discontinued with instruments operated by compressed air when soft tissue is damaged in the oral cavity.

Premature wear and malfunctioning from improper storage during

long periods of nonuse.

Reduced product life.

▶ The handpiece should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.

Risk due to incorrectly stored handpiece.

Injury and infection caused by inadvertent bur contact .

Damage to chucking system from dropping the handpiece.

After treatment, place the instrument properly in the handpiece nest, without the bur.

Burning hazard from hot handpiece head and instrument's head cap.

If the handpiece overheats, burns may arise in the oral area.

- Never contact soft tissue with the handpiece head.
- ▶ Do not use handpiece head as a cheek retractor.

Hazard from use as a light probe.

Do not use the device as a light probe with the bur rotating. The rotating

bur can cause injury.



For safety reasons, we recommend that the push button chuck system be checked before each use.

The following individuals are authorized to repair and service Lares Research products:

- Technicians at Lares Research
- Technicians specially trained by Lares Research

To ensure proper function, the highspeed handpiece must be set up according to the reprocessing (maintenance) methods described in this Lares Research Instructions for Use, and the care products and care systems described therein must be used.



Service may only be carried out by Lares Research-trained repair technicians using original Lares Research replacement parts.

4 First Use

▲ WARNING

Hazard from non-sterile handpieces.

Infection danger to the care provider and patient.

▶ Before first use and after each use, prepare and sterilize the handpiece.

Damage from soiled and moist cooling air.

Contaminated and moist cooling air can cause malfunctions and lead to premature bearing wear.

▶ Make sure that the supply of cooling air is dry, clean and uncontaminated.

4.1 Check the amount of water that flows from the handpiece

۲	Overheating of the tooth due to insufficient amount of cooling water.
	Insufficient spray water can cause the handpiece to overheat and
	damage the pulp and tooth.

- Adjust the water amount for the spray cooling to a minimum of 50 cm³ /min (3.1 inch³ /min).
- Check spray water ports and if necessary clean spray nozzles with the spray port cleaning tool (Cat No. 10541).

Drive pressure of 220 to 280 kPa (32 to 40 psi) is required to operate the handpiece. The air consumption is 42 to 55 NI/min. (1.1 to 1.9 cfm), drive air pressure of 220 kPa (32 psi) is recommended.

- Attach an air gauge (cat. no. 10062 for Lares MX/Kavo couplers & 10012for NSKcouplers & fixed back handpieces) and check the air pressure.
 - Drive air: 220 to 280 kPa (32 to 40 psi)
- Ensure the dental unit water pressure is set.
 - Water: 80 to 250 kPa (11 to 36 psi)
 - Water flow rate:≥50 ml/min at 11 to 36 psi
- Ensure that chip air pressure is set.
 - Chip air: 100 to 220 kPa (14 to 32 psi)
 - Chip air flow rate:≥1.5 NL/min at 14 to 32 psi



4.2 Attach the handpiece.

Accelerated materials in unanticipated directions.

The rotation of the handpiece has the potential to accelerate materials at high velocities in unanticipated directions that could affect the eye. The materials can be hard and sharp with the potential to damage unprotected eye. ► Use proper eve protection for the practitioner, staff and patient.

Risk due to procedure generated aerosols.

Air driven devices create a plume of bio contaminated air close to procedure site.

▶ Use proper face personal protective devices to reduce inhalation of aerosols.

5 Operation

Note: Along with appropriate maintenance of the dental unit water lines, the handpiece water line should be flushed for 20-30 seconds after each patient to reduce the risk of device contamination.

Transportation and storage conditions

	It is hazardous to start up the handpiece after it has been stored in a refrigerated environment. This can cause the handpiece to malfunction. ▶ Prior to start-up, very cold products must be heated to a temperature of 20°C to 25°C (68°F to 77°F).

5.1 Attach the Handpiece

Align the supply tubes on the back of the handpiece with the holes in the dental supply tubing and turn the threaded sleeve on the dental supply tubing clockwise until sleeve is tight.

Release of the handpiece during treatment.

A handpiece that is not properly attached can release dental tubing during treatment.

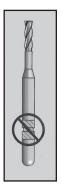
Before each use, check if the handpiece is securely onto to the dental supply tubing by pulling on it.



- 5.2 Remove the handpiece from dental supply tubing
- ► Hold the handpiece and turn the dental tubing sleeve counter clockwise until handpiece is released.
- 5.3 Insert the burs (carbides or diamonds) Note

Only use carbide or diamond burs that correspond to ISO 1797 type 3 that are made of steel or hard metal and meet the following criteria:

- Shaft diameter: 1.59 to 1.60 mm (0.0626 to 0.0630 inches)
- Shaft clamping length: 11 mm
- Do not use super short burs (less than 16mm length)
- Working part diameter: maximum 2 mm (0.080 inches)
- Do not use burs or diamonds with grooves on the shank (see figure).

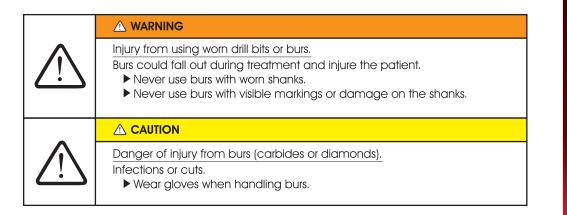


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Use of impermissible burs.

Injury to the patient or damage to the handpiece.

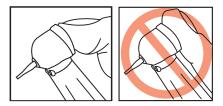
- ▶ Observe the instructions for use, and use the burs properly.
- Only use burs that do not have visible identifying grooves on the shank. (see figure 1 previous page)
- Never use carbide shank burs.
- ▶ Never use burs or tools with speed limit below maximum handpiece speed.



Hazard from worn or damaged push button chuck system.

The bur could fall out and cause injury.

- Pull on the bur to check that the chucking system is retaining the bur securely, use gloves or finger cots to prevent an injury or infection.
- Insert the bur gently into handpiece until it stops.
 Forcefully press the push button with your thumb.
 Push the bur all the way in until fully seated.
 Check that the bur is seated by pulling on it.
 Fully seat all burs completely into the chuck before use.





NOTE: Long fingernails may make bur changing difficult!

5.4 Removing the carbide or diamond bur

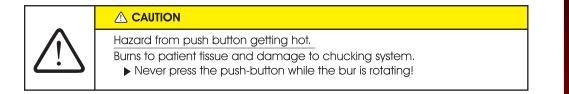
Hazard from rotating bur.

Lacerations.

Do not touch rotating bur!



- Remove the bur from the handpiece after treatment to avoid injury or infection while storing it.
- After the bur has stopped rotating, press the push-button with your thumb and simultaneously pull out the bur.



6 Reprocessing (Maintenance)

Limitations on Reprocessing

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. Have the highspeed handpiece inspected and serviced after 300 uses or once per year, whichever occurs first. **Note**

Definition of Reprocessing - all necessary steps that must be completed between uses.

6.1 Maintenance at the site of use (chair side)

 Hazard from non-sterile products. There is a risk of infection from contaminated handpieces. ▶ Take suitable personal protective measures (i.e. exam gloves, eye protection, 5 μm particulate filter mask).

- Remove all residual cement, composite or blood without delay.
- Clean and maintain the handpiece as soon as possible after treatment.
- ▶ Remove the bur from the handpiece.
- ▶ The handpiece must be dry when transported for cleaning and sterilizing.
- ▶ Do not submerge or place it in a solution or similar.

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6.2 Cleaning

Malfunctions from cleaning in the ultrasonic unit.

Ultrasonic cleaning may cause severe damage to the product. ► Only clean manually.

6.2.1 Cleaning: Manual cleaning - external Accessories required:

- Warm tap water
- Brush, e.g. medium-hard toothbrush or comparable nylon-bristled dental instrument cleaning brush



Manual cleaning process:

Handpiece disassembly not required.

- ▶ Rinse product under warm flowing tap water to remove gross soil.
- Brush off and rinse under flowing warm tap water to remove all visible soil.



- Use filtered pressurized air to completely dry handpiece. If soil is still visible when dry, repeat the initial cleaning steps.
- Apply Lares One-Step Handpiece Conditioner using the appropriate nozzle by attaching it to the handpiece and applying the conditioner for two seconds over a towel or sink.
- Install a shipping bur in handpiece and operate the handpiece for 45 seconds at full speed to expel excess lubricant.
- ▶ Remove excess conditioner from the exterior of handpiece with a towel.
- ▶ Remove the shipping bur from the handpiece.
- Cover the product with clean towel.

6.2.2 Cleaning: Automated external cleaning Not applicable.

6.2.3 Cleaning: Manual cleaning of the inside Not applicable.

6.2.4 Cleaning: Automated internal cleaning Not applicable.

6.3 Disinfection

\triangle	Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Handpiece damage may result. ▶ Never disinfect in a thermo-disinfector or manually.

6.3.1 Disinfection: Manual disinfection - external Not Applicable

6.3.2 Disinfection: Manual disinfection - internal Not Applicable

6.3.3 Disinfection: Machine disinfection - external and internal Not Applicable

6.4 Drying Manual Drying

▶ Blow off the outside and inside with compressed air until water drops are no longer visible. Automatic Drying Not Applicable 6.5 Care products and systems - Servicing

Sharp burs in the handpiece. Risk of injury from sharp or pointed burs. ▶ Remove bur before servicing.
Premature wear and malfunctions from improper servicing and care. Reduced product life. Perform proper care regularly!

Note

Lares Research only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

6.5.1 Care products and systems - Servicing: Care with Lares One-Step Handpiece Conditioner

Lares Research recommends applying handpiece conditioner after each time it is used, i.e. after each cleaning and before each sterilization.

- Remove bur.
- ▶ Use the appropriate nozzle attached to the handpiece conditioner.
- ▶ Insert the nozzle into the back of the handpiece and apply conditioner for two seconds while holding handpiece over at towel or sink.
- ▶ Insert a shipping bur in handpiece.
- ▶ Operate the handpiece for 45 seconds at full speed to expel excess lubricant.

6.5.1 Care products and systems - Servicing: (Continued)

- Remove excess conditioner from the exterior of handpiece with a towel.
- ▶ Remove the shipping bur from the handpiece.
- Cover the product with clean towel.

6.5.2 Cleaning the chuck

- ▶ Using knurled base, screw chuck cleaning nozzle onto <u>well shaken</u> can of Lares One-Step Handpiece Conditioner.
- Fully seat the tip of the nozzle into the chuck and maintain slight pressure.
- Direct the nozzle away from your body and towards an absorbent towel or trash can. Depress the One-Step Conditioner can top to spray for a minimum of two full seconds.
- If over-spray on towel appears discolored, spray again for an additional two seconds and repeat until discharge is clean.
- ▶ Wipe the excess conditioner from the handpiece with a clean dry towel.



6.5.3 Inspection and Function Testing: All handpieces: Visually inspect for damages and wear. Have serviced or discard damaged handpieces.

6.6 Packaging Prior to Autoclaving Note

The autoclave bag must be large enough for the handpiece so that the bag is not stretched.

The quality and use of the autoclave bag must satisfy applicable standards, be cleared to market and be suitable for the autoclave procedure!

Seal each handpiece individually in an autoclave bag!

6.7 Autoclaving Process handpieces in an autoclave.

	Premature wear and malfunctions from improper servicing and care. Reduced product life. ▶ Before each autoclave cycle, service the handpiece with Lares One-Step Handpiece Conditioner.

Contact corrosion due to moisture. Leaving handpiece in autoclave after cycle has finished may damage the product. Immediately remove the handpiece from the autoclave after the sterilization cycle to reduce condensation! **CAUTION** Do not use Flash Sterilization Techniques. These techniques are not validated for efficacy and damage to the handpiece may result.

The Lares Research handpiece has a maximum temperature resistance up to 135 °C (275 °F). Autoclave with gravitation process for at least 15 minutes at 132 °C \pm 1 °C (270 °F \pm 1.8 °F) Drying time: 15 minutes minimum.

When autoclaving multiple handpieces in one autoclave cycle ensure that the autoclave's maximum load is not exceeded. Follow the autoclave manufacturer's Instructions for Use.

Alternate validated sterilization cycle:

Forced (dynamic) air removal sterilization (pre-vacuum or steam pressure pulse) Cycle exposure time 4 minutes at 132 °C \pm 1 °C (270 °F \pm 1.8 °F) Drying time 30 minutes minimum. M

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6.8 Storage After Autoclaving

Cleaned and autoclaved handpieces should be stored protected from dust with minimum exposure to germs in a dry and cool space.

Note

The instructions provided above have been validated by Lares Research as being CAPABLE of preparing a handpiece for re-use. It remains the responsibility of the practitioner to ensure that the processing was actually performed using equipment, materials and personnel in the practitioner's facility to achieve the desired result. This requires validation and routine monitoring of the process, as specified by the autoclave manufacturer. Use only FDA cleared equipment and materials for autoclaving and routine monitoring.

Cross Infection Hazard.

Do not deviate from specified cleaning, autoclaving and storage procedures or patient and staff illness may occur.

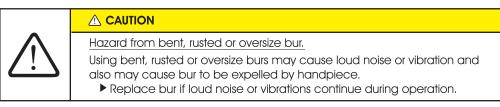
7 Troubleshooting

The inconvenience of handpiece downtime can often be avoided by following the common sense problem diagnosis and corrective action procedures that follow. If the problem cannot be corrected using these procedures, return the handpiece directly to Lares Research. (Outside U.S.A. return to your authorized Lares distributor). Do not attempt to perform procedures other than those described.

Safety note: If a serious safety event should occur during operation of this device it should be reported to Lares Research. It should also be reported to the regulatory authorities of the marketing region in which the user/patient is established.

RO U B L E S H 0 0 Ν G

7.1 Excessively loud or shrill operating noise or high vibration, chatter. Bent or damaged bur; replace bur with new one and operate handpiece.



Discard damaged or defective bur.

Dry bearings due to lack of lubrication.

- ► Lubricate handpiece with Lares One-Step Handpiece Conditioner. Worn or damaged bearings.
 - ▶ Replace turbine.

7.1 (cont.)

Hose kinked, twisted or blocked slowing turbine speed.

Straighten hose or replace if blocked.

7.2 Bur slips/walks out of chuck during operation.

Using incompatible burs with undersize shank diameters (at or worn below ISO 1.59-1.60mm); visual inspect for wear or damage.

Discard worn burs. Purchase burs with compliant shank diameters.

Using incompatible burs with carbide shank.

 Discontinue use of carbide shank burs. Purchase burs with steel shank materials.

Using incompatible burs with identifying grooves on the shank.

 Discontinue use of grooved burs. Purchase burs without identifying grooves.

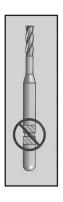
Chuck is worn from long use.

- Purchase replacement push button turbine or have handpiece repaired.
- 7.3 Low rpm and poor cutting power.

Hose kinked, twisted or leaking air; inspect entire length of hose.

▶ Straighten hose or replace if leaking.

Insufficient air pressure at handpiece; check air pressure at end of coupler using Lares air pressure gage.



► Adjust drive air pressure to 32-40 psi (220 - 280 kPa) at the end of handpiece tubing. Dry bearings due to lack of lubrication.

▶ Lubricate with Lares One-Step Handpiece Conditioner.

Worn or damaged bur or diamond.

- ▶ Replace bur or diamond and test cutting power.
- Discard worn or defective bur.

Turbine contaminated with debris due to dirty air supply.

- ▶ Flush repeatedly with Lares One-Step Handpiece Conditioner.
- ▶ Inspect air system dryers & filters for contamination; Install air system filtration if not present.

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7.4 Intermittent or spitting spray, insufficient spray pattern or poor water atomization.

Insufficient water flow.

Adjust water flow valve to increase water flow.

Insufficient atomization.

Make sure the chip air on your delivery system is turned on and set to 100 to 220 kPa (14 to 32 psi).

to 100 to 220 kPd (14 to 32 p Nonced water or air ports

Clogged water or air ports.

Clean out water spray ports or diffuser with spray port cleaning tool (cat. no. 10541) included with the handpiece.

Clogged dental unit water or air filters or screens.

Inspect and clean or replace clogged filters or screens.

Hose kinked, twisted or leaking.

▶ Straighten hose or replace if leaking.



Hazard from insufficient spray water.

Overheating of the medical device and damage to the tooth.

- Check the spray water channels and clean the spray nozzles with the spray port cleaning tool (cat. no. 10541) if necessary.
- ► Do not cut tooth without water spray.

_____!

7.5 Water leak at dental supply tubing connection.

Loose dental supply tubing connection.

► Make sure dental supply tubing sleeve is securely tightened on handpiece. Damaged handpiece gasket.

▶ Replace handpiece gasket.

7.6 Light output not sufficiently white (bright) Optic light guide output obscured by contamination.

Clean optic light element at front and rear of handpiece and end of swivel coupler with alcohol and cotton swab.

Light source bulb output discolored due to low intensity setting.

Replace source bulb or increase source intensity setting.



REPAIR SERVICE

For factory repair, send your handpiece directly to Lares Research, Attention: Technical Services Department, shipping prepaid (in USA only). For repair outside the USA, send your handpieces to your authorized Lares distributor.

8 Limited Warranty terms and conditions

The following warranty conditions apply to this Lares Research highspeed handpiece: Lares provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from date of purchase (60 months for Legacy 5 models), subject to the following conditions: In case of justified complaints, Lares will honor its warranty with a free replacement or repair performed by trained Lares tecnicians. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded.

In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary. Lares will not warranty and cannot be held liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, mineral deposits or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with Lares' instructions for use or other manufacturer's instructions.

Use of replacement or repair parts not manufactured by Lares Research may void this warranty. No liability is assumed when defects or their consequences are derived from manipulations or changes to the product by the customer or a third party. Service warranty claims will only be accepted when product is submitted directly to Lares Research, attention: Technical service department, shipping prepaid (in USA only). The serial number must be clearly visible on the product. For warranty repairs outside the USA, contact your local authorized Lares distributor.

Disposal

Prior to disposal, the product must be reprocessed (sterilized) per this instruction.

The Lares handpiece you purchased is a highly calibrated product, designed to function properly only with genuine parts manufactured by Lares. Use of parts not manufactured by Lares is strictly probited.

	 Hazard from non-Lares replacement parts. Use of non-genuine parts not manufactured by Lares will void the Lares Limited Warranty, and their use may cause malfunction that could lead to serious patient injury. This handpiece performs properly when maintenance and repair are performed with genuine Lares parts installed in accordance with the instructions accompanying the parts.

Please contact Lares or your authorized distributor for all maintenance and repair questions.

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9 Replacement parts and Accessories

Description	Catalog Number
Replacement Ceramic CX Turbine Including Wrench (557/757)	10005-036/10071-036
Handpiece Gasket (fixed back handpieces only)	10009
4/5 Hole Air Pressure Gauge (fixed back & NSK connection handpieces only)	10012
MX Swivel Air Pressure Gauge (Lares MX & Kavo MULTIflex swivel handpieces only)	10062
One-Step Handpiece Conditioner	10083
MX Swivel Handpiece Conditioner Nozzle (Lares MX & Kavo MULTIflex swivel handpieces only)	10085
Head Cap Wrench	10308
Kit, Quad-Port, O-ring, Diffuser	10341
Tool, Quad-Port Diffuser	10342
Lube Nozzle for Chuck, 4-Hole Backend, & Lowspeeds (fixed back & swivel)	10361
NSK Connection Conditioner Nozzle (NSK connection handpieces only)	11634
O-ring Replacement Kit (NSK connection handpieces only)	11636
Head Cap Assembly, Ceramic CX Turbine (557/757)	13360/11593

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