Smoothdrive 1:5 & 1:1 Contra-angles

Instructions for use

Precision Performance

REF 13502, 13503 **RX Only**

CE * 1639

Lares Research
295 Lockheed Ave
Chico, CA 95973

EU REP MDSS Schiffgraben 41, 30175 Hannover, Germany

Not Sterile

Device Specifications

⚠ Caution

It is essential to use dry, purified compressed air in order to ensure the long working life of the device. Maintain the quality of the air and water by regular maintenance of the compressor and filtration systems. The use of unfiltered hard water will lead to early blockage of the tubes, connectors and spray ports.

Type:
13502: Dental contra-angle 1:5 speed increasing (red ring) with light, push-button grip chuck, and internal spray.
13503: Dental contra-angle 1:1 speed direct drive (blue ring) with light, push-button latch-type chuck, and internal spray.

Intended Use:
Product intended for professional use only. Use for general dentistry restorative and prophylactic work. Any use other than that for which this device is intended is prohibited and may prove dangerous.

Classification:
Class 1 in accordance with FDA, Class IIa in accordance with European Directive 93/42/EEC concerning medical devices.

Type of coupling:
ISO 3964 with internal spray and light in the motor.

Transmission ratio:
13502 - Red ring: speed increasing (1:5)
13503 - Blue ring: direct drive (1:1)

Motor speed:
Maximum 40,000 rpm

Bur Rotation speed:
13502 - Red ring: maximum 200,000 rpm
13503 - Blue ring: maximum 40,000 rpm

Cooling air:
To ensure that your contra-angle or straight handpiece/micro motor unit functions with maximum efficiency, it must be cooled by an air supply of 5-10 NL/min at 36.2 to 71 psi (250 – 490 kPa) from the nose of the micro-motor.

Light:
The contra-angle handpieces are fitted with a fused glass light guide that has very good resistance to sterilization.

Spray air and water:
Spray water flow minimum 50ml/min at 29 psi (200kPa). Do not exceed 40 psi.
Spray air flow minimum is 1.5 Nl/min at 29 psi (200kPa). Do not exceed 40 psi.

Bur:

1:5 contra-angle (red ring)
Only use burs that correspond to ISO 1797 type 3 that meet the following criteria:
- Shaft diameter: 1.59 to 1.60 mm (0.0626 to 0.0630 inches)
- Shaft clamping length: 11mm
- Do not use burs or diamonds with grooves on the shank.
- Do not use burs with carbide shanks.

1:1 contra-angle (blue ring)
Only use burs that correspond to ISO 1797 type 2 that meet the following criteria:
- Shaft diameter: 2.348 to 2.350 mm (0.0924 to 0.0925 inches)
- Minimum chuck length: 12.8 mm (0.504 inches)
- Maximum bur length: 22.5mm (0.8858 inches)
- Maximum bur tip diameter: 4 mm (0.157 inches)

Device Operation

⚠ Caution

- After inserting a bur, and before use, check that the bur is securely retained by pulling on the bur. Follow the bur manufacturer's instructions, and do not exceed the maximum recommended rpm for each instrument.
- Before each use, verify that the push-button head cap is securely retained.
- The device must not be started without a bur inserted into the chuck. Never mount an instrument on a rotating motor.
- Insert a bur. Idle the contra-angle (run without cutting) for 10 seconds before cutting.
- Pointed and sharp instruments should be handled with great caution.

Changing the bur (*Figure 1*):
1:5 contra-angle (friction grip chuck): Press the push-button with the tip of your thumb and at the same time pull the bur out. To fit a new bur, press the push-button and insert the bur to fully seated position.

1:1 contra-angle (latch-type chuck): Insert the bur until it stops. Depress the push button. Gently rotate the bur while applying forward pressure until it aligns and slides forward into place. Release the push button.

⚠ Caution - IMPORTANT SAFETY INFORMATION - READ BEFORE USE!

Electric dental motors have much more power than air motors or turbines and can generate excessive heat in worn, damaged or poorly maintained contra-angles. Serious patient burns can occur when contra-angles overheat during patient treatment. Burns may go undetected by dentist or patient until after tissue damage has occurred because the anesthetized patient cannot feel the tissue burning and the dentist is insulated from the heated contra angle by the handpiece housing.

To avoid patient injury:
- Always use water spray when treating patients with contra-angle.
- 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 contamination.
- Electric contra-angle must be lubricated after each use. Maintain according to instructions for use. Train office staff to properly clean and maintain the contra-angles. Implement a method for tracking that proper maintenance is performed for each instrument.
- Examine electric contra angle before EACH use for excessive heat, noise or vibration. Immediately stop using any suspect contra-angle and contact Lares Research at 1-888-333-8440, ext. 4 to arrange repair.
- Make sure burs are fully seated, do not extend burs.
- Do not use worn burs.
- To avoid overheating of the push-button, which could cause patient burns, it should not be pressed inadvertently while the instrument is rotating. Soft tissue (tongue, cheek, lips, gums, etc.) must be protected by deflection with a shield, retractor or a dental mirror.
- Insufficient cooling leads to overheating of the tooth and damage to the pulp. Be sure to only operate with >50 ml/min water spray volume.
- Do not use water to cool contra-angle after removal from autoclave as rapid contraction could damage product.

Maintenance

NOTE: We recommend using Lares One-Step Handpiece Conditioner (item #10083)

⚠ Caution

- The instrument is delivered "non-sterile".
- Before using for the first time and within a maximum of 30 minutes after each treatment, clean and lubricate the instrument, then autoclave. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from beingblocked.
- Do not immerse in an ultra-sonic bath.
- Use only Lares Research provided maintenance products and parts or those recommended by Lares Research. Using other products or parts may cause operational failure and/or void the warranty.
- Wearing of personal protective equipment (gloves, goggles etc.), should be complied with by dental personnel using or performing maintenance of medical devices that are contaminated or potentially contaminated.
- Pointed and sharp instruments should be handled with great caution.
- Check that the sterilizer and the water that is used are clean. After each sterilization cycle, remove the device from the sterilizing apparatus immediately in order to reduce the risk of corrosion.
- In the event of prolonged disuse, the instrument must be stored in a dry environment. Lubricate and sterilize the instrument before reuse.

Clean and Disinfect the Handpiece Exterior
1. Disconnect the instrument from the drive motor and remove the bur.
2. Holding handpiece head upward, carefully scrub the external surface with a soft brush under running warm tap water 40˚C ± 5˚C (104˚F ± 10˚F) to remove visible debris and particles. Be careful not to run water into back end tubes. *Figure 2*
3. Wipe the handpiece with disinfectant wipe.
4. Dry with a towel or dry syringe air.

NOTE: Lares Research recommends the following disinfectant CaviWipes® (manufactured by Metrex). After cleaning, if the moisture is present, wipe off with dry cloth or blow it off with compressed air until there is no moisture in the interior and exterior. When blowing off with compressed air, cover the handpiece with cloth to prevent scattering of water.

⚠ Caution

When using disinfectant, follow the instructions given by the Manufacturer of the disinfectant.

Clean Water Port Spray
Insert the port clearing tool into each of the four water spray ports and rotate the tool in a circular motion to clean and dislodge any debris. *Figure 3*

Clean and Lubricate Chuck
Using a well-shaken can of Lares One Step Conditioner, with chuck cleaning nozzle (item #10361) attached, fully seat nozzle tip into chuck and apply conditioner for one spray of approximately 1/2 second over a towel or sink.
Figure 4

Clean and Lubricate Back End of Handpiece
- Place the instrument in a cloth or over a sink to catch any lubricant, debris and foreign matter expelled by the atomizer jet.
- Insert the Electric Attachment Nozzle (item #10084) into the back end of the handpiece. *Figure 5*
- Spray for one spray of approximately 1/2 second.

Expel Excess Lubricant
- Insert a bur or test pin in the chuck mechanism of the instrument.
- Pull on the bur to make sure it is securely retained.
- Attach the handpiece to the motor.
- Hold the handpiece in a vertical position with the head pointed down to allow excess conditioner to drain out.
- Operate for 1 minute starting at the lowest speed and gradually ramping up to a maximum speed of 100,000 rpm for 1:5 contra-angle (red ring) or 20,000 rpm for the 1:1 contra-angle (blue ring) to distribute and expel excess conditioner.

⚠ Caution

When expelling excess conditioner, never operate the 1:5 contra-angle (red ring) above 100,000 rpm or the 1:1 contra-angle (blue ring) above 20,000 rpm without water cooling spray on or contra-angle could overheat and become damaged. Always use water cooling spray while treating patients regardless of speed.

Sterilization

⚠ Caution

The FDA & CDC strongly recommend that handpieces be heat sterilized after each patient use.

- Lubricate before each sterilization.
- Thermal disinfection not recommended.
- The quality of the sterilization depends very much on the cleanliness of the device. Only sufficiently clean devices may be sterilized.

1. Remove the bur before sterilization.
2. Insert into autoclave bag, one handpiece per bag.
3. Lares Research has validated a gravity type steam autoclave cycle of 132 C˚(270F)˚ for 15 minutes with a drying time of 30 minutes.

Alternate validated sterilization cycle:
Forced (dynamic) air removal sterilization (pre-vacuum or steam pressure pulse)
Cycle exposure time 4 minutes at 132 C (270 F) drying time 30 minutes minimum

NOTE: Temperature should not exceed 275˚ F (135˚C). Follow autoclave manufacturer's instructions.

4. After autoclave cycle is completed, remove instrument immediately and allow to dry. Allow to cool down 30 minutes prior to handling.

⚠ Caution

Do not use water to cool contra-angle after removal from autoclave as rapid contraction could damage product.

Clean Fiber Optics

When handpiece is cool to the touch, gently CLEAN fiber optic light transmitting surfaces on both ends of handpiece with cotton swab dampened with isopropyl alcohol.
Figure 6a and 6b.

Warranty and Service

Toll Free Ordering & Technical Assistance: (888) 333-8440

Non Toll-Free Worldwide: (530) 345-1767

Internet & Online Ordering: www.laresdental.com

There are no user-serviceable parts in the Lares Research Smoothdrive contra-angles.

For authorized repair, send your handpiece directly to Lares Research (in U.S.A. only), shipping pre-paid. For repair outside the U.S.A. send your handpiece to your authorized Lares distributor.

Lares Research recommends you have the device checked every 300 autoclave cycles or once per year.

Warranty

Each Lares Research Smoothdrive contra-angle is warranted against defects in materials and workmanship for a period of 2 years from the date of purchase.

Additional Conditions of Warranty

1. Warranty registration is automatic as of shipping date (Outside the US warranty registration may be required).
2. The contra-angle must be operated and maintained in accordance with procedures outlined in these instructions.
3. The contra-angle must not be subjected to abuse or neglect.
4. The contra-angle must not be repaired or disassembled by anyone other than Lares Research or your authorized Lares distributor. Lares Research will repair or replace at its discretion without charge, any defective parts covered by this warranty provided the Smoothdrive contra-angle is returned to the factory, transportation prepaid. (Outside the US return to your authorized Lares distributor.) Lares Research makes no other warranties expressed or implied.

*CE mark only applies to 1:5 contra angle, not 1:1 contra angle.

General Precautions

The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:

- must only use operating devices that are in perfect working order. In the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact repair center.
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

Excess material from products used for maintenance (lubricants, cleaning products and disinfectants) originating from the contra angle may penetrate into the electric motor and interfere with its functioning. It is essential to follow the maintenance instructions accompanying each product.

SERIOUS EVENT (INJURY OR NEAR INJURY) NOTIFICATION

If a serious event occurs during the operation of this device it should be reported to Lares Research. In the European Union it should also be reported to the competent authority of the Member State in which the user and/or patient is established.

⚠ Caution

The device must not be used in the presence of open lesions, injury to soft tissue or recent extractions. The exhaust air could propel infected material into the wounds and cause infections and risk embolism.
Adhere to the instructions for use, in accordance with the instructions of the bur manufacturer. Never use a bur with an incorrect diameter, as there is a risk of becoming detached during treatment and causing injury to yourself, to your patient and to third parties.
The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorized and may be dangerous. The medical device meets all the current legal requirements.

Contraindications

None

Transportation, Storage and Disposal

Transport and storage conditions

Temperature between-40C (-40F) and 70C (158F), relative humidity between 10% and 100%, atmospheric pressure 50 kPa to 106kPa (7.3 to 15.3 psi).

Disposal

Always reprocess the product after last use and prior to disposal. If you do not know your local disposal laws, send the product with its original packaging material (if available) to Lares service depot for proper disposal and recycling.

Accessories

Item #

10084 - Electric Attachment Nozzle
10361- Push Button Chuck Conditioner Nozzle
10083- Handpiece Conditioner

Questions?
Call 1-888-333-8440, Ext. 1
Lares Research
295 Lockheed Avenue
Chico, CA 95973 USA
www.laresdental.com

Symbol Description

REF Catalog Part Number	CE XXXX Conformity Marking
SN Product Serial Number	Manufacturer
EC REP European Community Representative	YYYY-MM Manufacture Date
Consult Accompanying Documents	Parts Applied to Patient
	132°C Steam Autoclave

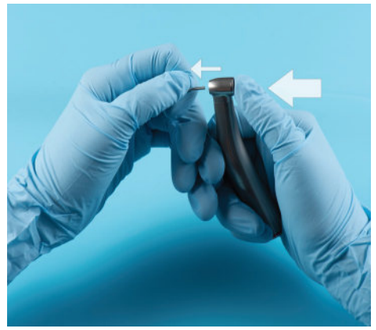


Figure 1:
Photo of contra-angle push button chuck being activated to remove bur with arrows.

Figure 2:
Photo of cleaning external surface of the handpiece with soft bristled brush.

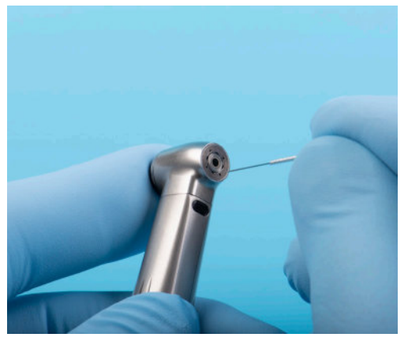
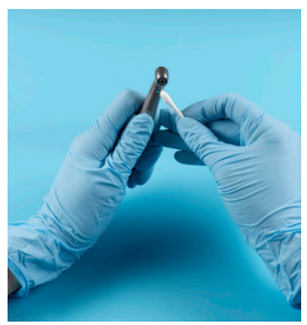


Figure 3:
Photo of clearing water ports with provided tool.

Figure 4:
Photo of chuck cleaning nozzle spraying conditioner into chuck of a contra-angle.

Figure 5:
Photo of lube can with nozzle inserted into back of a contra-angle



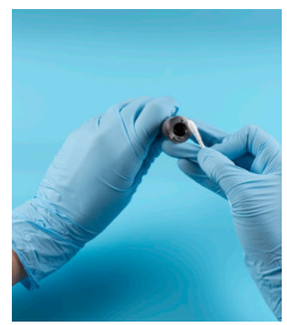


Figure 6a and 6b: Photo of fiber optics being cleaned at both ends with cotton swab.