GuidedSMILE™

Instructions for Use

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Purpose of this Document

This document gives general guidance on the preparation (cleaning and sterilizing / disinfecting) of medical devices supplied by GuidedSMILE. It also gives guidelines for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

Instructions for Use: – GuidedSMILE Surgical Guides

WARNING: Surgical Guides are not delivered or marked sterile, and should be inspected, cleaned (if necessary), and cold-sterilized/high-level disinfected prior to use.

PRODUCT DESCRIPTION

Surgical Guides	(Pin Guide, Fixation Base, Osteotomy Guide, & Carrier Guide) – A collection of patient-matched devices, produced from biocompatible materials, which aid in the preparation and placement of dental implants.

INTENDED USE

Surgical Guides	(Pin Guide, Fixation Base, Osteotomy Guide, & Carrier Guide) are intended to be used to assist in anatomical visualization, surgical treatment planning, and intraoperative surgical procedures (e.g., orientation of implant components, guiding of surgical instruments).
Pin Guide	• The Pin Guide is the first step of the CHROME GuidedSMILE surgical process. It sets the stage of the whole surgery and ensures that the surgery starts accurately. • Its only purpose is to deliver the Fixation Base and maintain its position while the fixation pins are set. • Dentate Pin Guides seat on the teeth, are verified via occlusal windows and ensure the surgery starts in the correct position. • With edentulous patients, the pin guide will seat exactly like the denture and verifies the bite and ultimate tooth position.
Fixation Base	• The Fixation Base is the second step of the CHROME GuidedSMILE process and sets the foundation for the surgery. • All subsequent components clip into the CHROME Locs on the Fixation Base. • It is unique in the industry because it is made of CR/CO which means rigidity and stability. • The Fixation Base is designed using our patent pending floating guide technology, meaning the guide does not contact bone, rather is supported by divergent pin placement. • The Fixation Base's initial function is bone reduction. The upper edge of the Fixation Base has been carefully created to indicate the level to which the bone needs to be reduced. • The second function of the Fixation Base is to support the

	components: Osteotomy Guide, Carrier Guide, Nano-Ceramic Prosthetic, and RAPID Appliance.
Osteotomy Guide	• The Osteotomy Guide is the third step of the CHROME GuidedSMILE surgical process. • All CHROME cases come with an Osteotomy Guide. It controls the kit's spoons or drills during osteotomy creation. • Our guides control the implant depth, trajectory, and indexing (rotation). • It seats into the Fixation Base and is fixed using the proprietary CHROME Locs. • CHROME GuidedSMILE works with any implant systems that offers has a fully- or semi-guided kit. Fully guided kits allow the user to place the implant through the guide. A complete list of guided kits is available on the upload area of our web site. When you upload you case, chose the system.
Carrier Guide	• The Carrier Guide is the fourth step of the CHROME GuidedSMILE surgical process and is a plastic guide that serves many functions. • Once the Osteotomy Guide has been removed the Carrier Guide affixes to the Fixation Base by use of the CHROME Locs. • One function of the Carrier Guide is to serve as a tissue gap between the top of the bone reduction to the bottom of the Carrier Guide. • It also serves as a key indicator to the direction of the implants, the rotation of the implants, and the direction of the multi-unit abutment screw that attaches the abutment to the implant. • Angled implants are identified on the Carrier Guide by way of notches at the osteotomy site. • The Carrier Guide remains in the mouth through the prosthetic conversion. • The two clear plastic extrusions on the Carrier Guide delivers the prosthetic in the proper position as planned.
Prosthesis	• The CHROME provisional is the printed, immediate load, long-term prosthetic that is delivered during the day of surgery. It is esthetic, patient-pleasing appliance. • It is a natural-looking, beautiful, strong provisional. • Easy to adjust. Accepts composite, bonding agents, acrylic and VOCO, Stellar, Duralay, GC pattern resin luting materials. • It is designed from a smile simulation using proprietary tooth libraries. • It is designed for long-term post-surgical patient use. • Provides the perfect prototype for the final restoration.

Composition (Primary)	Pin Guide & Carrier Guide: MED610 Resin Fixation Base & Osteotomy Guide: Mediloy RPD (CoCr) Prosthesis: Lucitone Digital Value 3D Economy Tooth and Trial Placement Resin
Indications for Use	GuidedSMILE Surgical Guides are indicated for use in dental procedures aiming to place implants or prosthetics in fully or partially edentulous patients. They are indicated for use in the oral cavity by dental professionals.
Contraindications	Contraindicated in cases with known allergies or hypersensitivity to chemical ingredients in the following material(s): MED610 Resin, Mediloy RPD (CoCr)
Inspection and Cleaning	Visually inspect surgical guides, with magnification if needed, to ensure that they are free of debris. If not, manually clean prior to cold-sterilization/high-level disinfection.
Manual Cleaning (if required)	Presoak in isopropyl alcohol (IPA) (Do not exceed 5 min. soak). Brush away remaining debris. Rinse with clean water and allow to fully dry before placing into any sealed containers (if applicable).
WARNING	Surgical Guides cannot be disinfected properly unless they are thoroughly cleaned; free of debris.

High-Level Disinfection (Cold-Sterilization): Manual process using MetriCide™ OPA Plus

Note: These disinfection instructions are based on the MetriCide OPA PLUS Instructions for Use. Refer to MetriCide OPA PLUS package insert prior to product use for complete instructions.

No Activation is Required	Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container can be used for up to 75 days (providing the 75 days does not extend past the expiration date listed on the container) until used. Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the MetriCide OPA Plus Solution Test Strip indicates a concentration above the MRC.
High-Level Disinfection	Immerse device completely, filling all lumens and eliminating air pockets, in MetriCide OPA Plus Solution for a minimum of 12 minutes at 20°C (68°F) or higher to destroy all pathogenic microorganisms. Remove device from the solution and rinse thoroughly following the rinsing instructions below.

Rinsing Procedure	• Following removal from MetriCide OPA Plus Solution, thoroughly rinse the semi-critical medical device by immersing it completely in a large volume (e.g. 9 liters) of water. Use sterile water if available, otherwise potable water is acceptable. • Keep the device totally immersed for a minimum of one minute in duration, unless a longer time is specified by the reusable device manufacturer. • Manually flush all lumens with large volumes (not less than 100 mL) of rinse water unless otherwise noted by the device manufacturer. • Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. • Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove MetriCide OPA Plus Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE, LARGE-VOLUME WATER IMMERSION RINSES ARE REQUIRED.
Monitoring of Germicide	• During reuse, it is recommended that the MetriCide OPA Plus Solution be tested with the MetriCide OPA Plus Test Strips prior to each use. This is to ensure that the Minimum Recommended Concentration (MRC) of ortho-phthalaldehyde is present. • During the usage of MetriCide OPA Plus Solution as a high-level disinfectant, it is recommended that the thermometer and timer be utilized to ensure that the optimum conditions are met.
Post-Processing Handling and Storage of Reusable Devices	Disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination.
Caution	• Disinfection instructions are provided above for convenient reference. Always follow the instructions stated by the manufacturer of the disinfectant. • Failure to follow rinsing instructions exactly has resulted in reports of chemical burns, irritation, and staining of the mouth, throat, and esophagus and stomach.

USE

Before using, make sure:	Examine surgical guides for defects prior to and during use. Any surgical guide that shows defects should be evaluated for risk impact prior to continued use. Using a surgical guide with defects may cause the guide to break or cause injury.

FOR MORE INFORMATION

Visit www.GuidedSMILE.com

Printed copy available upon request.

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Instructions for Use: –
Surgical Guide Drills and Pins

WARNING: Drills and Pins are not delivered or marked sterile, and should be inspected, cleaned (if necessary), and sterilized prior to use.

PRODUCT DESCRIPTION

CHROME Drill	Fixture/appliance dental drill bit A shaft of metal intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance.
CHROME Pin	Dental implantation drilling template retention pin A small, metal peg designed to provide initial stability to anchor a custom-made surgical template that is fitted over the ridge of existing teeth and/or gum of the patient during the first stage of a dental implantation procedure. It is inserted through lateral guide hole(s) in the template, and is pressed into pre-drilled hole(s) in the jawbone. It is used for implantation procedures where a tooth/teeth are missing and a template is used to provide the dentist with the correct drilling position(s) for the implant(s).

INTENDED USE

CHROME Drill	CHROME Drills are intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the placement of custom-made surgical guide templates to be used in the implantation of a dental fixture/appliance.
CHROME Pin	CHROME Pins are intended to be used in dental surgery to provide stability or anchor a custom-made surgical template that is fitted over the ridge of existing teeth and/or gum of the patient during the first stage of a dental implantation procedure. Pins are inserted through lateral guide hole(s) in the template, and is pressed into pre-drilled (CHROME Drills) hole(s) in the jawbone.
Composition	1.4197 (420F) Stainless Steel
Indications for Use	CHROME Drills and Pins are indicated for use in dental procedures aiming to place implants or prosthetics in fully or partially edentulous patients. They are indicated for use in the oral cavity by dental professionals.

Contraindications	Contraindicated in cases with known allergies or hypersensitivity to chemical ingredients in the following material(s): 1.4197 (420F) Stainless Steel
Inspection and Cleaning	Visually inspect drills and pins, with magnification if needed, to ensure that they are free of debris. If not, manually clean prior to sterilizing.
Manual Cleaning (if required)	Presoak in enzymatic cleaner to loosen debris (5 min.). Brush away remaining debris. Rinse (2 min.), dry with absorbent lint free towel.
WARNING	Drills and Pins cannot be sterilized properly unless they are thoroughly cleaned; free of debris.

STERILIZATION

Autoclaving	Drills and Pins may be sterilized by using a dynamic air removal sterilization cycle. Sterilize in a FDA approved pouch at full cycle with a dwell at 132ºC / 270ºF minimum for 4 minutes and dry time of 30 minutes.
Caution	Use sterilizing devices according to the manufacturers' recommended procedure. It is the responsibility of the user to ensure that sterilization is effective.

USE

Before using, make sure:	Examine drills/pins for defects/excessive wear prior to and during use. Any drill/pin that shows defect/wear should be removed from service and discarded. Using a drill/pin with defect/wear may cause the drill to break or cause injury.

FOR MORE INFORMATION

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Symbol Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

Non-sterile

Consult instructions for use

Manufacturer

Date of manufacture

Catalogue number

Medical device

Batch code

Rx Only

For prescription use only

Unique Device Identifier

Do not re-use