Dentsply Maillefer
Chemin du verger 3
CH – 1338 Ballaigues
Switzerland

For dental use only

GB

DIRECTION FOR USE
HEDSTROEM COLORINOX - A016D

1) INDICATIONS FOR USE
These product are for Dental use only.
These instruments / products have to be used only in a clinical or hospital environment, by qualified users.
Application field:
Root canal file for manual preparation of the root canal.

2) CONTRAINDICATIONS
None known

3) WARNINGS
None known

4) PRECAUTIONS
This product must be sterilized before use and between each use using the indicated disinfection and cleaning instructions.

5) ADVERSE REACTIONS
In the present technical state, no adverse reaction has been reported so far.

6) STEP-BY-STEP INSTRUCTIONS
Not applicable

7) WARRANTY
No warranty defined for this product.

Expiry date
Keep bag intact with product until end use.
Storage conditions
No Storage conditions indicated

8) DISINFECTION, CLEANING AND STERILIZATION
See general instructions in appendix

	Symbols
	Expiry date
	See directions for use
	The upper and lower limits of temperature of use, storage and transportation

Manufacturer :

Dentsply Maillefer
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Russian Representative
Представительство компании
Дентсплай Россия Лимитед., Москва, ул. Проспект Мира д.6,
тел (495) 988-28-25

➔ **Visit our website: www.dentsplymaillefer.com**

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DISINFECTION, CLEANING AND STERILIZATION

Reprocessing procedure for dental instruments and implantable radicular devices

Foreword
For hygiene and sanitary safety purposes, all instruments not marked “sterile” must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well as the subsequent ones.

Area of application
Disinfection and sterilisation before first usage and reprocessing procedures concerning:

A1. Instruments:
Cutting instruments, (hand and engine driven) such as:
- Endodontic instruments (files, broaches, reamers, enlargers, endodontic burs, ultrasonic inserts);
- Rotary cutting instruments (Diamond burs, tungsten carbide burs, stainless steel drills, carbon steel burs).

Root canal filling instruments (Pluggers, spreaders, compactors);
Supports, kits and instrument organisers
Hand instruments and clamps.

A2. Implantable devices:
Dentinal and radicular posts made of steel, titanium and glass fibers.
Supports, kits and organiser systems for posts.

A3. Contra angle

B. Filling material: Only chemical disinfection (no sterilisation)
Gutta percha, Thermafil obturation devices.

Exclusion
- Equipment such as Motors, Apex locators and other devices with reprocessing procedures included in the individual Direction for Use.
- MTA, Glyde, TopSeal.

General recommendation

1 - Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer. For all metal instruments, it is recommended to use anticorrosion disinfecting and cleaning agents
2 - For your own safety, please wear personal protective equipment (gloves, glasses, mask).
3 - The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.
4 - Limitations and restrictions on reprocessing :
The individual DFU indicates if the useful life of a device might be reduced by the number of reprocessing cycles.
Furthermore, the appearance of defects such as cracks, deformations (bent, twisted), corrosion, loss of colour coding or marking, are indications that the devices are not able to fulfil the intended use with the required safety level.
5 - Single use marked instruments are not approved for re-use.
6- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
7 - Tungsten carbide burs, plastic supports, hand instruments and NiTi instruments are degraded by Hydrogen Peroxide (H_2O_2) solution.
8 - NiTi Instruments are degraded if immerged more than 5 minutes in a solution of NaOCl at more than 5%.
9 - Instruments made of aluminium are degraded in presence of caustic soda solutions with mercury salt. Do not use acid (pH < 6) or alkaline (pH > 8) solutions.
10- The washer-disinfector is not recommended for instruments made of aluminium, tungsten carbide or carbon steel.

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Step-by-step procedure

A. Devices

							A3. Contra Angle
						A2. Implantable devices	
					A1. Instruments		
				Following uses			
			First use				
	Operation	***Operating mode***	***Warning***				
1.	Disassembling	- Disassemble the device, if required	Silicone stops have to be removed.		X		
2.	Pre-Disinfection	- Soak all instruments immediately after use in a detergent and disinfecting solution combined with proteolytic enzyme if possible.	- Follow instructions and observe concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on instruments). - The disinfecting solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. - Do not use disinfecting solutions containing Phenol or any products which are not compatible with the instruments (See general recommendations). - For visible impurities observed on instruments a pre-cleaning is recommended by brushing them manually with soft material.		X		
3.	Rinsing	- Abundant rinsing (at least 1 min)	- Use quality water in accordance with local regulations. - If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the cleaning.		X		
4a.	Automated Cleaning with washer-disinfector	- Place the devices in a kit, support or container to avoid any contact between instruments or posts. - Put them in the washer-disinfector (Ao value > 3000 or, at least 5 min at 90 °C).	- Discard any instruments with large obvious defects (broken, bent). - Avoid any contact between instruments or posts when placing in the washer-disinfector use kits, supports or container. - Follow instructions and observe concentrations given by the manufacturer (see also general recommendations). - Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly.	X	X	X	X
OR							
4b	Manual Cleaning or assisted by an ultrasonic device	- Place the devices in a kit, support or container to avoid any contact between instruments. - Immerse in the disinfecting solution with cleaning properties, assisted by an ultrasonic device if suitable.	- No visible impurities should be observed on the instruments. - Discard any instruments with large obvious defects (broken, bent, and twisted). - Follow instructions and observe concentrations and time given by the manufacturer (see also general recommendations). - The disinfecting solution should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.	X	X	X	
5.	Rinsing	- Abundant rinsing (at least 1 min)	- Use quality water in accordance with local regulations. - If a disinfecting solution contains a corrosion inhibitor, it is recommended to rinse the instruments just before the autoclaving. - Dry on a single use non-weaved cloth, or with a drying machine or filtered compressed air.	X	X	X	
6.	Inspection	- Inspect devices and sort out those with defects. - Assemble the devices (stops)	- Dirty instruments must be cleaned and disinfected again. - Discard instruments which show any deformations (bent, twisted), damages (broken, corroded) or defects (loss of colour coding or marking) affecting the resistance, the safety or the performance of the instrument or posts. - Protect carbon steel bur with corrosion inhibitor before packaging. - For Contra Angle : lubricate the device with an adequate spray before packaging	X	X	X	X
7.	Packaging	- Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilisation pouches”.	- Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which are resistant up to a temperature of 141°C (286°F) and in accordance with EN ISO 11607.	X	X	X	X

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			A3. Contra Angle				
			A2. Implantable devices				
			A1. Instruments	***Following uses***			
				First use			
	Operation	***Operating mode***	***Warning***				
8.	Sterilization	- Steam sterilisation at: 134 °C / 273°F during 18 min.	- The instruments, posts and the plastic supports must be sterilized according to the packaging labelling. - Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Use a validated sterilisation procedure according ISO 17665 - Respect the maintenance procedure of the autoclave device given by the manufacturer. - Use only this recommended sterilization procedure. - Control the efficiency (packaging integrity, no humidity, colour change of sterilisation indicators, physico-chemical integrators, digital records of cycles parameters). - Traceability of procedure records	X	X	X	X
9.	Storage	- Keep devices in sterilization packaging in a dry and clean environment	- Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and validity period).	X	X	X	X

B. Filling material

1.	***Operation***	***Operating mode***	***Warning***
	Disinfection	- Immerse the obturation devices in NaOCl (2,5 % at least) during 5 mn at ambient temperature.	- Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material (See general recommendation).