CLEANING, DISINFECTION AND STERILISATION PROTOCOL

(Endodontics Instruments, Burs, Post remover Kit, …)

INTRODUCTION	F.F.D.M PNEUMAT products are supplied NON STERILE. For this reason, they must be cleaned, disinfected and sterilised before first use or re-use, to prevent contamination.
SCOPE	All products in the "B2" handpiece range and all instruments mounted on a contra-angle. Applicable to products in the following ranges: – REAMING: Endodontic instruments: K-Files, reamers, hedstrom Files, etc – STOMATOLOGY: stainless steel surgical burs (Not applicable) – FILLING: LENTULO spiral, DYNA paste, Paste fillers, etc.) – ASSESSMENT : – OPENING: Gates drill, Peeso reamer – POST REMOVER KIT : Universal kit for extracting pins.
STANDARDS	See the next page
RE-TREATMENT LIMITATIONS	Sterilisation has very little effect on the products. However, in accordance with regulatory requirements, the products' 5-year life span can vary depending on wear or damage to components from use or **after 10 sterilisation cycles**. The appreciation of the quality of products and their use is the user's responsibility.
GENERAL RECOMMANDATIONS	– It is the user's responsibility to sterilise products before first use and re-use. – For your safety, we recommend using EPIs (Individual Protective Equipment) - for example: Gloves, eye protection – Only use disinfectants with proven effectiveness (Solutions included in the DGHM list, EU labelling, FDA approved) If you notice marks or stains, clean the instrument with a wipe first.

INSTRUCTIONS

PLACE OF USE	Dental clinic
STORAGE AND TRANSPORT	No specific requirements It is recommended re-treating instruments as soon as possible after use
PREPARATION FOR CLEANING	No specific requirements All instruments must be detached from pins. However, pins do not need to be dismantled. Dispose of instruments that are defective (broken, bent, not cutting any more, etc.)
DISINFECTION	Immerse products in a disinfectant bath using ultrasound if required.
RINSING & DRYING	Rinse instruments abundantly in distilled or demineralized water and then dry.
OPERATIONAL CHECKS AND TESTS	Jointed instruments: Check that joints move (rotation link for pin) freely with no excessive "play" Also check that the tightening mechanism is working properly. (tightening screw). Ensure that cleaning is done properly, if applicable, clean again.
PACKAGING	After disinfection, put instruments in sterilisation sachets. (Check that sachets comply with EN ISO 11607-1 standard)
STERILISATION	**Steam sterilise in an autoclave for 18 minutes at 134°C.** The autoclave must comply with current standards NF EN 13060+A2, maintenance and upkeep conditions must be complied with in accordance with manufacturer's instructions.
STORAGE	No specific requirements as stainless steel is used, however, **it is preferable to store devices in a clean, dry place protected from damp.**
ADDITIONAL INFORMATION	When several instruments are sterilised in a single autoclave cycle, ensure that the maximum load of the autoclave is not exceeded.

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SUMMARY

	REAMING				STOMATOLOGY				CAVITY		EXPLORATION		FILLING		OPENING		POST REMOVER	
	Carbon steel		NiTi		Carbon steel		Stainless steel											
First use	✓		✓		✓		✓		✓		✓		✓		✓		✓	
Re-use		✓		✓		✓		✓		✓		✓		✓		✓		✓
Disinfection	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Rinsing	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Drying	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Checks and tests	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Packaging	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Sterilisation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Protection with anticorrosive film	-	-	-	-	✓	✓	-		✓	✓	-	-	-	-	-	-	-	-
Dry place	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

PICTOGRAMS

WARNING - This symbol is used to mean "Attention, see instructions"*

LOT - The symbol must be accompanied by the manufacturer's lot code. Lot code and the symbol must be adjacent.

KEEP DRY - Keep away from rain

MANUFACTURER - The symbol must be accompanied by the name and address of the manufacturer - person who places the device on the market

CONSULT THE MANUAL

NON STERILE

STAINLESS STEEL

CARBON STEEL

NICKEL TITANIUM

STANDARDS :

- **NF EN ISO 13485 :** Système de management de la qualité pour les dispositifs médicaux
- **NF EN ISO 9001 :** Système de management de la qualité
- **Directive européenne 93/42/CEE :** du 14 Juin 1993 relative aux dispositifs médicaux
- Règlement sur les dispositifs médicaux **DORS/98-282**
- **NF EN ISO 1639 :** Dispositifs médicaux pour l'art dentaire
- **NF EN 980 :** Symboles utilisés pour l'étiquetage des dispositifs médicaux
- **NF EN ISO 14971 :** Application de la gestion des risques aux dispositifs médicaux
- **NF EN ISO 17664 :** Informations devant être fournies par le fabricant pour le processus de restérilisation des dispositifs médicaux

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