

Information concerning the symbols used for labeling, packaging, and instructions for use:

	Symbol	Designation	Description	Reference/ISO registration number
Identification of economic operators		Manufacturer	Identifies the manufacturer of the medical device (name and address). Note: If a date is next to this symbol, this corresponds to the date of manufacture. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-3082)
		Authorized representative (authorized representative in the European Union)	Identifies the manufacturer's European authorized representative (name and address).	ISO 15223-1
		Importer	Identifies the importer of the medical device (name and address).	ISO no. 7000-3725
		Distributor	Identifies the distributor of the medical device (name and address).	ISO no. 7000-3724
General symbols		Medical device	Indicates that this is a medical device.	(EU) 2017/745 Annex I, Article 23.2(q)
	 fkg.ch/ifu	Operating instructions	Indicates the need for the user to consult the operating instructions and/or the processing instructions for FKG devices, as well as this document, made available on FKG Dentaire's website.	ISO 15223-1 (ISO no. 7000-1641)
		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions to be taken that cannot be presented on the medical device itself.	ISO 9687 (ISO no. 7000-0434A)
Product identification and other information specific to each batch		Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 (ISO no. 7000-2493)
		Batch code	Indicates the manufacturer's batch code so that the batch can be identified.	ISO 15223-1 (ISO no. 7000-2492)
		UDI code (Unique Device Identification)	Indicates the UDI code and UDI carrier specific to the device.	(EU) 2017/745 Annex I, Article 23.2(h)
		Quantity	Indicates the quantity contained in the packaging.	Not applicable
		Use-by date	Indicates the date after which the medical device is not to be used. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2607)
		Date of manufacture	Indicates the date on which the medical device is manufactured. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2497)

Symbol	Designation	Description	Reference/ISO registration number
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 (ISO no. 7000-1051)
	Indicator of number of possible remaining uses	Indicates the number of possible remaining uses of the instrument.	Not applicable
	Clockwise rotation	Indicates that an instrument is intended to be used in a clockwise direction. This symbol is accompanied by a rotational speed expressed in revolutions per minute [rpm].	ISO 21531 (ISO no. 7000-0258)
	Reciprocating movement (counterclockwise)	Indicates that an instrument is intended to be used in a reciprocating movement with a counterclockwise result.	Not applicable
	Material symbol	Indicates the material from which the device is made: Nickel-titanium alloy Stainless steel Silicone Plastic Aluminum	ISO 9687 (ISO no. 7000-2793)
	Tip diameter	Indicates the tip diameter of an instrument, expressed in hundredths of a millimeter.	Not applicable
	Taper	Indicates the taper of an instrument, expressed in millimeters per millimeter of length (e.g., .02 corresponds to 2 %)	Not applicable
	Length	Indicates the usable length of the device.	Not applicable
	Thickness	Indicates the thickness of the device.	Not applicable
	Width	Indicates the width of the device.	Not applicable
	File Type K	Identification symbols for endodontic instruments: File Type K.	ISO 3630-1
	File Type K Flex	Identification symbols for endodontic instruments: File Type K Flex.	Not applicable
	Reamer Type K	Identification symbols for endodontic instruments: Reamer Type K.	ISO 3630-1
	Reamer Type K Flex	Identification symbols for endodontic instruments: Reamer Type K Flex.	Not applicable
	File Type H	Identification symbols for endodontic instruments: File Type H.	ISO 3630-1
	File Type H Flex	Identification symbols for endodontic instruments: File Type H Flex.	Not applicable

	Symbol	Designation	Description	Reference/ISO registration number
Information relating to sterility and (re)sterilization		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 (ISO no. 7000-2502)
		Single sterile barrier system	Indicates that the device is packaged in a single sterile barrier system.	(EU) 2017/745 Annex I, Article 23.3(a) (ISO no. 7000-3707)
		Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 (ISO no. 7000-2606)
		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 (ISO no. 7000-2609)
		Sterilizable in a steam sterilizer (autoclave) at temperature specified	Indicates that the medical device is sterilizable in a steam sterilizer (autoclave) at the temperature specified.	ISO 9687 (ISO no. 7000-2868)
Identification of the intended use		Accessory	Indicates that this is an accessory.	Not applicable
		Cavity preparation	Indicates that this is a device used for access cavity preparation.	ISO 21531 (ISO no. 7000-2856)
		Removal of old fillings	Indicates that this is a device used for endodontic retreatment.	ISO 21531 (ISO no. 7000-2857)
		Working on fillings	Indicates that this is a device used for working on fillings.	ISO 21531 (ISO no. 7000-2858)
		Crown preparation	Indicates that this is a device used for prosthetic restoration.	ISO 21531 (ISO no. 7000-2859)
		Root canal treatment	Indicates that this is a device used for root canal treatments.	ISO 21531 (ISO no. 7000-2861)
Other symbols		CE marking	European conformity marking for Class I medical devices.	(EU) 2017/745 Annex V and 93/42/EC Annex XII
		CE marking	European conformity marking for Class > I medical devices, accompanied by the identification number of the notified body. Notified body no. 1639: SGS Belgium NV.	
		Empty alveolus	Indicates that the blister alveolus is empty	Not applicable



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