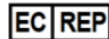




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iTero Element Sleeve Instruction for Use

The following symbols may appear on iTero Element sleeves packaging and may appear within this document

Device complies with Council Regulations (EU) 2017/754 for Medical Devices	Expiry date	"Rx only" CAUTION: US Federal Law restricts this device to sale by or on the order of a licensed Dentist, Orthodontist, or Dental Professional. The system serves as a prescription medical device should be operated by qualified health-care providers only.
Medical device needs to be protected from moisture	Need to consult the instructions for use – IFU is available on website www.itero.com	
Keep away from sunlight	Catalogue number	
Temperature limits to which the medical device can be safely exposed	Parts or accessories on which this symbol occurs should not be reused	
Item is a medical device	Batch code	

WARNING: To prevent cross contamination, it is essential that the wand and cradle are fully cleaned and disinfected after each patient, as described in the *iTero Element User Manual*.

WARNING: For single use only. Do not re-use.
To prevent cross contamination, it is essential to replace the iTero Element Sleeve after each patient.

iTero Element Scanner Sleeve is suitable for the iTero Element family of products. It is a single patient use disposable component intended for use as a cover to the iTero's Scanning Unit to prevent cross contamination during the scanning procedure and to protect the optical window of the wand.

iTero Element sleeves may be used on patients classified as Preadolescent, Adolescent, and Adult. Using the iTero Sleeves together with iTero Element systems provide important advantages over existing crown-production methods, including powder-free scanning, greater crown-production accuracy, and immediate feedback during the scanning process. Refer to our website www.itero.com to learn how the iTero Service can enhance your business by increasing patient satisfaction, improving clinical outcomes, and enhancing office efficiency.

Safety instructions

iTero sleeve is supplied non-sterile and should not be sterilized before usage. iTero sleeves comply with ISO 10993 Biocompatibility international standard.

CAUTION: Dispose of scanner sleeves according to standard operating procedures or local regulations for disposal of contaminated medical waste.

Any serious incidents related to the iTero device should be reported to Align Technology Ltd. and the competent authority of the Member State in which the user and patient are established.

Replacing a Disposable Sleeve



1) Pressing lightly on the center of the sleeve, pull the sleeve slowly off the wand and discard



Warning - optical surface! DO NOT touch the optical surface. Contact may cause damage. Clean and disinfect the wand, as described in System user manual, section 10.2



2) Gently slide the new sleeve onto the Scanning Unit until it clicks into place.

Note: If the scanner is not to be used immediately afterwards, attach the blue protective sleeve.