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iTero Lumina™ Pro Wand Barrier Sleeves Instructions for Use



Safety Instructions:

- WARNING** The iTero Lumina Pro wand barrier sleeves are intended for single use only. Do not reuse.
- WARNING** The iTero Lumina Pro wand barrier sleeves are intended for single use and must be disposed of and replaced after each patient in order to reduce the risk of cross-contamination.
- WARNING** To reduce the risk of cross contamination, it is essential that the iTero Lumina Pro scanner is fully cleaned and disinfected immediately after each patient, and that the iTero Lumina Pro wand barrier sleeve is replaced between patients, as described in the *iTero Lumina Pro User manual*.
- WARNING** If you notice any damage, do not use the iTero Lumina Pro wand barrier sleeves and contact Customer Support.
- CAUTION:** Do not use the iTero Lumina Pro wand barrier sleeves after the expiry date.
- CAUTION:** Dispose of iTero Lumina Pro wand barrier sleeves according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
- iTero Lumina Pro wand barrier sleeves are supplied as non-sterile and should not be sterilized before usage.
- iTero Lumina Pro wand barrier sleeves comply with the applicable parts of ISO 10993 Biocompatibility international standard.

The following symbols may appear on the iTero Lumina Pro wand barrier sleeves packaging:

	Medical device manufacturer.		Consult the instructions/electronic instructions for use.	Rx ONLY	CAUTION: Rx Only. 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 and should be operated by trained dental health-care providers only.
QTY	Quantity		Use-by date.		
	Keep away from direct sunlight	REF	Catalogue number.	UDI	Unique device identifier.
	Temperature limit.		Do not re-use.	MD	Medical device.
	Keep dry.	LOT	Batch code.		Country of manufacture (including date of manufacture).

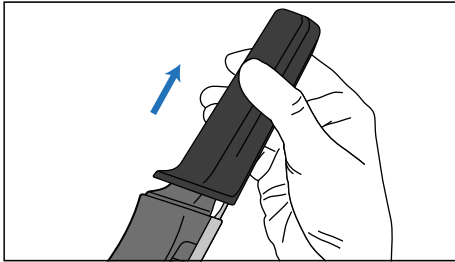
iTero Lumina Pro wand barrier sleeves are suitable for the iTero Lumina Pro products. They are a single-use disposable component intended for use as a cover to the iTero Lumina Pro wand tip to reduce the risk of cross-contamination and to protect the optical window of the wand during the scanning procedure.

iTero Lumina Pro wand barrier sleeves may be used on patients classified as Children, Adolescents, and Adults.

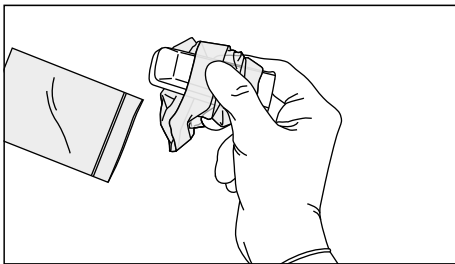
Any serious incidents in relation to the iTero™ device should be reported to Align Technology Ltd., and the competent authority of the Member State in which the user and patient are established.

Applying a new wand barrier sleeve

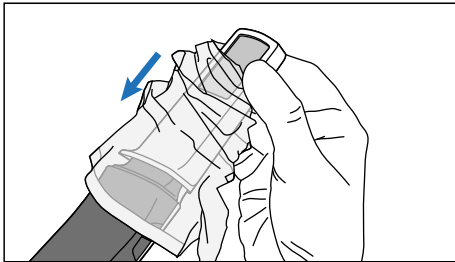
- 1) Place a new wand barrier sleeve in its original packaging near the iTero Lumina Pro wand.
Note: Inspect the packaging to verify that there is no visible damage. Replace it if any damage is observed.
- 2) Gently remove the protective sleeve from the wand.



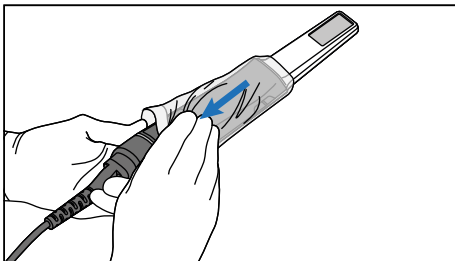
- 3) Wearing gloves, remove the wand barrier sleeve from its packaging, making sure to keep the transparent sheath folded.



- 4) Slide the rigid section of the wand barrier sleeve onto the optical tip of the wand until you feel a “click”, making sure that the transparent sheath is not pinched between the rigid section of the wand barrier sleeve and the wand.



- 5) Gently pull the transparent sheath to cover the entire wand.

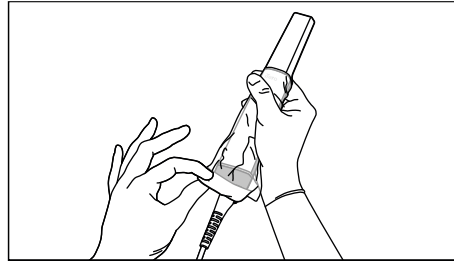


Note: The white tape on the transparent sheath is for manufacturing purposes only, and should be ignored.

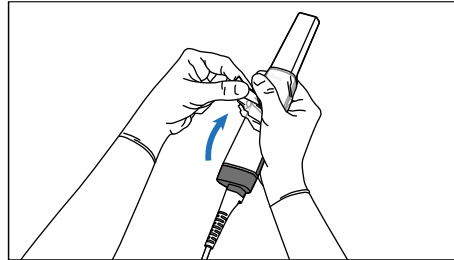
- 6) Visually inspect the wand barrier sleeve for any noticeable damage, for example, cracks, scratches, and holes. Replace the wand barrier sleeve in case of noticeable damage.

Removing the wand barrier sleeve

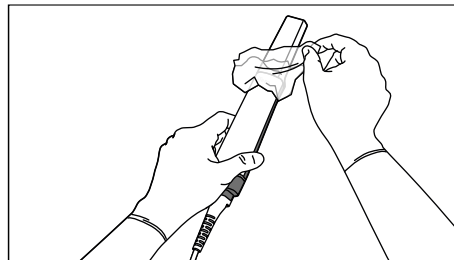
- 1) Wearing new gloves, hold the wand firmly in one hand, and with your other hand, grasp the white tape at the bottom of the transparent sheath with your thumb and forefinger.



- 2) Pull the transparent sheath towards the tip of the wand.

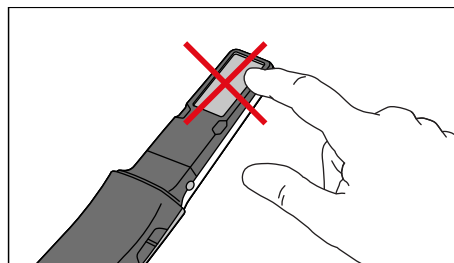


- 3) Firmly hold the bottom of the wand and with your other hand pull the transparent sheath to remove the wand barrier sleeve from the wand.



Note: OPTICAL SURFACE!

DO NOT touch the optical surface of the wand as this may cause damage. If additional cleaning, besides that described in the *iTero Lumina Pro User manual* is necessary, use the anti-static cloth found inside the wand barrier sleeve box.



- 4) Clean and disinfect the wand, as described in the *iTero Lumina Pro User manual*.
- 5) A new wand barrier sleeve may be applied to the wand after cleaning and disinfection have been performed. If the scanner will not be used immediately after cleaning and disinfection, attach the dark protective sleeve.

Refer to our website www.itero.com to learn how the iTero™ Service can enhance your business by increasing patient satisfaction, improving clinical care, and enhancing office efficiency.

