Brief Summary Document

Product

MOSES™ D/F/L Family of Delivery Fibers – IFU #UM-20061740EN, Rev. C

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The MOSES fibers are intended for use with the compatible laser systems in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy. For the safe use of the fibers, read and comprehend these instructions and the appropriate laser system operator's manual before use.

CONTRAINDICATIONS

Refer to the Laser Console User Manual for contraindications that may be specific to each surgical specialty.

WARNINGS AND PRECAUTIONS

- Never inspect the fiber while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Do not pull on the fiber when it is connected to the laser.
- Avoid clamping or clipping any devices such as a hemostat onto the fiber.
- Avoid any contact of metallic instruments with the fiber tip.
- Ensure that the scope port is open prior to inserting the fiber into the scope.
- Ensure laser calibration maintenance was performed according to Lumenis' recommendations, and that it supports all types of MOSES fibers. An uncalibrated system may lead to fiber damage.
- Avoid direct laser beam contact with accessories. Baskets, guidewire, and other ureteroscopic accessories may be damaged.
- Avoid bending the fiber above the maximum bending radius (refer to Specifications section), as it may lead to energy loss and damaged to the endoscope.

- Do not use the fiber if the sterile packaging is opened or damaged. Do not use if labeling is incomplete or illegible. If necessary, return the fiber to the supplier for replacement.
- Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
- A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Ensure the fiber is properly handled so that it is not damaged by being stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled.
- Do not clamp the fiber with a hemostat or other instruments.
- If sterile tape is used to secure the fiber, always remove the tape before lifting the fiber.
- Do not touch the tip of the fiber connector.
- When removing the protective cap, hold the laser connector, not the strain relief or fiber-optic cable. Pulling on the strain relief or fiber-optic cable may damage the fiber and result in unintended laser exposure.
- Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.
- At any energy setting, the repetition rate should be adjusted so as not to exceed the power specification listed in the specifications table. The maximum allowed energy for the MOSES 200 D/F/L fiber is 2J.
- Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage, fire in the treatment room personnel or patient. Refer to the appropriate laser operator manual for detailed safety information.
- The fiber must not be reprocessed and/or re-used. Invisible debris may remain on the fiber that can heat up during use, causing possible destruction of the fiber or injury to the patient. 1
- Re-sterilization and use of the fiber more than once can lead to degradation of the fiber's performance envelope, creating a possible injury hazard to the patient.

ADVERSE EVENTS/COMPLICATIONS

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Brief Summary Document

Product

MOSES™ D/F/L LP Family of Delivery Fibers – IFU #UM-20108280, Rev. C

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The MOSES D/F/L LP fibers are intended for use with the compatible laser systems in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy. For the safe use of the fibers, read and comprehend these instructions and Lumenis Pulse™ 60H system operator's manual before use.

CONTRAINDICATIONS

Refer to the Laser Console User Manual for contraindications that may be specific to each surgical specialty.

WARNINGS AND PRECAUTIONS

- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of Holmium lasers.
- When inspecting the fiber while it is connected to the laser, use only the aiming beam and always point it towards a non-reflective surface and away from people in the OR.
- Do not pull aggressively on the fiber when it is connected to the laser.
- Avoid clamping or clipping any devices such as a hemostat onto the fiber.
- Avoid any contact of metallic instruments with the fiber tip.
- Ensure that the scope port is open prior to inserting the fiber into the scope.
- Ensure laser calibration maintenance was performed according to Lumenis' recommendations, and that it supports all types of MOSES fibers. An uncalibrated system may lead to fiber damage.
- Avoid direct laser beam contact with accessories. Baskets, guidewire, and other ureteroscopic accessories may be damaged.

- Avoid bending the fiber above the maximum bending radius (refer to Specifications section), as it may lead to energy loss and damaged to the endoscope.
- Do not use the fiber if the sterile packaging is opened or damaged. Do not use if labeling is incomplete or illegible. If necessary, return the fiber to the supplier for replacement.
- Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
- A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Ensure the fiber is properly handled so that it is not damaged by being stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled.
- Do not clamp the fiber with a hemostat or other instruments.
- Do not touch the tip of the fiber connector.
- When removing the protective cap, hold the laser connector, not the strain relief or fiber-optic cable. Pulling on the strain relief or fiber-optic cable may damage the fiber and result in unintended laser exposure.
- Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.
- At any energy setting, the repetition rate should be adjusted so as not to exceed the power specification listed in the specifications table. The maximum allowed energy for the MOSES 200 D/F/L LP fiber is 2J.
- Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage, fire in the treatment room personnel or patient. Refer to the appropriate laser operator manual for detailed safety information.
- The fiber must not be reprocessed and/or re-used. Invisible debris may remain on the fiber that can heat up during use, causing possible destruction of the fiber or injury to the patient.
- Re-sterilization and use of the fiber more than once can lead to degradation of the fiber's performance envelope, creating a possible injury hazard to the patient.

ADVERSE EVENTS/COMPLICATIONS

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Brief Summary Document

Product

SlimLine™ Family of Delivery Fibers – IFU 51731888-01A

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

Lumenis SlimLine fibers are intended for use with the compatible lasers in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue, and for lithotripsy. For the safe use of the fibers, read and comprehend these instructions and the appropriate laser operator's manual before use.

CONTRAINDICATIONS

Refer to the laser operator manual for contraindications that may be specific to each surgical specialty.

WARNINGS

- When inspecting the fiber while it is connected to the laser, use only the aiming beam and always point it towards a non-reflective surface and away from people in the OR. Accidental laser exposure can cause severe eye damage.
- A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Ensure the fiber is properly handled so that it is not damaged by being stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled.
- Do not clamp the fiber with a hemostat or other instruments.
- At any energy setting, the repetition rate should be adjusted so as not to exceed the power specification listed in the specifications table.

Additional warnings and precautions can be found in the product labeling supplied with each device.

POTENTIAL ADVERSE EVENTS

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

URO-1220403-AB Jul 2024

Brief Summary Document

Product

SlimLine™ 200 D/F/L Fiber – IFU #UM-10024820EN, Rev. B

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The SlimLine 200 D/F/L fibers are intended for use with the compatible lasers in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy. For the safe use of the fiber, read and comprehend these instructions and the appropriate laser operator manual before use.

CONTRAINDICATIONS

Refer to the Laser Console User Manual for contraindications that may be specific to each surgical specialty.

WARNINGS AND PRECAUTIONS

- Never inspect the fiber while it is connected to the laser. Accidental laser exposure can cause severe eye damage.
- Ensure that the scope port is open prior to inserting the fiber into the scope.
- Do not pull on the fiber when it is connected to the laser.
- Avoid clamping or clipping any devices such as a hemostat onto the fiber.
- Avoid any contact of metallic instruments with the fiber tip.
- Ensure laser calibration maintenance was performed according to Lumenis' recommendations. An uncalibrated system may lead to fiber damage.
- Avoid direct laser beam contact with accessories. Baskets, guidewire, and other ureteroscopic accessories may be damaged.
- Avoid bending the fiber above a 6mm bending radius, as it may lead to energy loss and damage to the endoscope.

- Do not use the fiber if the sterile packaging is opened or damaged. Do not use if labeling is incomplete or illegible. If necessary, return the fiber to the supplier for replacement.
- Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
- When removing the protective cap, hold the laser connector, not the strain relief or fiber-optic cable. Pulling on the strain relief or fiber optic cable may damage the fiber and result in unintended laser exposure.
- Do not remove the protective cap from the laser connector in the sterile field. Removing the protective cap in the sterile field may compromise sterility.
- Do not touch the tip of the fiber connector.
- A damaged fiber-optic cable may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Ensure the fiber is properly handled so that it is not damaged by being stepped on, pulled, lefty lying in a vulnerable position, kinked or tightly coiled.
- Do not clamp the cable with a hemostat or other instruments.
- If sterile tape is used, always remove the tape before lifting the cable.
- At any energy setting, the repetition rate should be adjusted so as not to exceed the power specification listed in the specifications table. 1
- Improper use of the fiber or use of a damaged fiber may result in severe eye or tissue damage, fire in the treatment room, or accidental laser exposure to the treatment room personnel or patient. Refer to the appropriate laser operator manual for detailed safety information.
- The SlimLine 200 D/F/L fiber must not be reprocessed and/or re-used. Invisible debris may remain on the fiber that can heat up during use, causing possible destruction of the fiber or injury to the patient.
- Re-sterilization and use of the SlimLine 200 D/F/L fiber more than once can lead to degradation of the fiber's performance envelope, creating a possible injury hazard to the patient.

ADVERSE EVENTS/COMPLICATIONS

Refer to the Laser Console User Manual for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Brief Summary Document

Product

SlimLine™ LP Family of Delivery Fibers – IFU #UM-20108270, Rev. D

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The SlimLine LP fibers are intended for use with the compatible lasers in surgical procedures involving open, laparoscopic, and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue and for lithotripsy. For the safe use of the fibers, read and comprehend these instructions and Lumenis PulseTM 60H system operator's manual before use.

CONTRAINDICATIONS

Refer to the Laser Console User Manual for contraindications that may be specific to each surgical specialty.

WARNINGS AND PRECAUTIONS

- Laser surgical procedures should be performed only by individuals adequately trained in laser surgery and clinical use of Holmium lasers.
- When inspecting the fiber while it is connected to the laser, use only the aiming beam and always point it towards a non-reflective surface and away from people in the OR. Accidental laser exposure can cause severe eye damage.
- Do not pull aggressively on the fiber while it is connected to the laser.
- Avoid clamping or clipping any devices such as a hemostat onto the fiber.
- Avoid any contact of metallic instruments with the fiber tip.
- Ensure laser calibration maintenance was performed according to Lumenis' recommendations, and that it supports all types of SlimLine LP fibers. An uncalibrated system may lead to fiber damage.

- Avoid direct laser beam contact with accessories. Baskets, guidewire, and other ureteroscopic accessories may be damaged.
- Avoid bending the fiber above the maximum bending radius (refer to Specification section) as it may lead to energy loss and damage to the endoscope.
- Do not use the fiber if the sterile packaging is opened or damaged. Do not use if labeling is incomplete or illegible. If necessary, return the fiber to the supplier for replacement.
- Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
- A damaged fiber may cause accidental laser exposure or injury to the treatment room personnel or patient, and/or fire in the treatment room.
- Ensure the fiber is properly handled so that it is not damaged by being stepped on, pulled, left lying in a vulnerable position, kinked or tightly coiled.
- Do not clamp the cable with a hemostat or other instruments.
- At any energy setting, the repetition rate should be adjusted so as not to exceed the power specification listed in the specifications table.
- A single-use fiber must not be reprocessed and/or re-used. Invisible debris may remain on the fiber that can heat up during use, causing possible destruction of the fiber or injury to the patient.
- Re-sterilization and use of a single-use fiber more than once can lead to degradation of the fiber's performance envelope, creating a possible injury hazard to the patient.
- The fiber face should be free of pits, scratches, discoloration, or debris. Using the fiber with such defects may destroy the fiber and damage the laser.

ADVERSE EVENTS/COMPLICATIONS

Refer to the laser operator's manual for adverse events/complications that may be specific to each surgical specialty.

Precautions can be found in the product labeling supplied with each device.

Brief Summary Document

Product

Xpeeda™ D/S/L Fiber – IFU #PB-10008200, Rev. D

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable Instructions for Use for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The Xpeeda D/S/L fiber is intended for use with the compatible lasers in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, coagulation of soft tissue. For the safe use of the fiber, read and comprehend these instructions and the appropriate laser operator manual before use.

CONTRAINDICATIONS

The Xpeeda D/S/L fiber is contraindicated for treatment of patients for whom endoscopic procedures are contraindicated. Refer to the laser operator manual for contraindications that may be specific to each surgical specialty.

WARNINGS AND PRECAUTIONS

- In order to avoid damage to the endoscope, it is recommended to position the fiber's distal metal tip at the distal end of the endoscope prior to laser activation.
- Ensure that all orientation and positioning markings are visible on the video screen, indicating that the fiber's distal tip is located beyond the distal end of the endoscope.
- In the unlikely event that the metal cap detaches during use, locate the detached metal cap and remove it using forceps. Irrigate area well to remove any debris.
- Improper use of the Xpeeda D/S/L fiber or use of a damaged fiber may result in severe eye or tissue damage; fire in the treatment room; or accidental laser exposure to the treatment room personnel or patient. Refer to the appropriate laser operator manual for detailed safety information.

- When using a fiber-optic delivery device, always inspect it to ensure that it has not been fractured, or otherwise damaged. The fiber may be damaged, kinked or punctured, if stepped on, pulled, left lying in a vulnerable position or tightly coiled. Do not clamp the fiber with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the fiber. A damaged fiber may cause accidental laser exposure, injury or burns to treatment room personnel or patient, and/or fire in the treatment room.
- To avoid damage to the fiber:
    - Ensure that the scope port is open prior to inserting the fiber into the scope.
    - Avoid bending the fiber, particularly when holding the handle or manipulating the scope.
    - Avoid clamping or clipping any devices such as a hemostat on to the fiber.
    - The Xpeeda fiber is designed for use in an aqueous environment only. Do not use the fiber in air, and do not bury the tip in tissue. Both conditions do not provide an adequate aqueous environment for proper cooling of the tip and will permanently damage the fiber.
- To avoid damage to accessory devices:
    - Avoid direct laser beam contact with accessories. Baskets, guidewire, and other ureteroscopic accessories may be damaged.
- Careful handling of the fiber during setup is important to prevent fiber damage. Fiber damage may impact fiber performance.
- Never activate the laser if the fiber tip is not extended beyond the end of the scope and the position and orientation markings are not visible.
- Laser fibers are consumable devices and performance degrades with use. Various factors influence fiber life and degradation, such as tissue composition, tissue mass and surgical technique. Total energy transmission through the fiber will vary depending upon these factors.
- Do not sterilize the Xpeeda fiber.

ADVERSE EVENTS/COMPLICATIONS

For the safe use of the fiber, read and comprehend these instructions and the appropriate laser operator manual before use.

Precautions can be found in the product labeling supplied with each device.