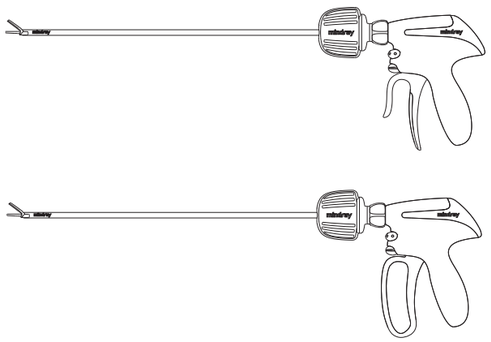
mindray

Ultrasonic Surgical Instrument

Instructions for Use



1.1 Product Models

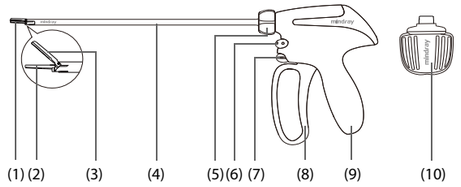
14 series	23 series	36 series	45 series	7 mm Vessel Sealing*
POS-14	POS-23	POS-36	POS-45	Configured
PCT-14	PCT-23	PCT-36	PCT-45	Not configured
FOS-14	FOS-23	FOS-36	FOS-45	Not configured
FCT-14	FCT-23	FCT-36	FCT-45	Not configured
FC-14	FC-23	FC-36	FC-45	Configured
FCH-14	FCH-23	FCH-36	FCH-45	Configured
FOK-14	FOK-23	FOK-36	FOK-45	Configured
FOM-14	FOM-23	FOM-36	FOM-45	Configured
PC-14	PC-23	PC-36	PC-45	Configured
PCH-14	PCH-23	PCH-36	PCH-45	Configured
POK-14	POK-23	POK-36	POK-45	Configured
POM-14	POM-23	POM-36	POM-45	Not configured
FO-14	FO-23	FO-36	FO-45	Configured

NOTE

- **The trigger type, scale silkscreen, and activation count function vary among models. This IFU includes information related to all features of the instrument. Some features may not be available on your instrument.**
- **All the instruments can seal vessels up to and including 5 mm in diameter. Instruments configured with the 7 mm vessel sealing function can be used to seal vessels up to and including 7 mm in diameter.**

1.1.1 Product Components

Take an ultrasonic surgical instrument with O-type trigger as an example:



(1) Jaws: clamp tissue

(2) Blade: outputs energy

(3) Tissue pad and clamp arm: enables tissue holding and clamping

(4) Shaft sleeve: protects the shaft

(5) Rotation wheel: allows the shaft sleeve and the jaws to rotate 360 degrees to cut tissue in different directions

(6) MAX button: activates the MAX mode. This button and the MIN button cannot be pressed at the same time.

(7) MIN button: activates the MIN mode or controls the Enhanced Vessel Sealing (EVS) function

(8) Trigger: controls the opening, closing, and clamping of the jaws

(9) Grip: is used for gripping

(10) Torque wrench: is used to tighten or loosen the connection between the transducer and ultrasonic surgical instrument

1.1.2 Intended Purpose

The Ultrasonic Surgical Instruments are indicated for soft tissue incisions and sealing vessels in open and endoscopic surgery.

1.1.2.1 Indication for Use

The ultrasonic surgical instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired in general, plastic, pediatric, gynecologic, urologic, thoracic, and other open and endoscopic procedures, as well as procedures exposed to orthopedic structures (such as spine and joint space). Some instruments allow for the sealing of vessels up to and including 7 mm in diameter, using with Enhanced Vessel Sealing.

1.1.2.2 Intended Patient Populations

The product can be applicable for adults, pediatric patients. The attending physician must decide whether the foreseen application is admissible based on the general condition of the patient.

1.1.2.3 Intended Medical Conditions

The Ultrasonic Surgical Instrument is used in medical institutions.

1.1.2.4 Contra-indications

The instruments are not indicated for incising bone.

The instruments are not indicated for tubal coagulation.

1.1.2.5 Clinical Benefits

Compared with traditional surgical instruments, the product can reduce operation time and bleeding in clinical use.

1.2 Safety Information

WARNING

- **This ultrasonic surgical instrument is compatible only with transducer and generator specified by Mindray. Using other transducer or generator may cause product damage, patient injury, or failure to meet the claimed specifications.**
- **The instrument meets the requirements of type CF applications. Medical devices or accessories used with the instrument should at least meet the requirements of IEC 60601-1.**
- **Check if the instrument and its package are intact. Do not use it if any damage is detected.**
- **Temporarily unused instrument shall not contact the patient, medical personnel, or any flammable material. Unused high-temperature instrument may cause patient or operator burns.**
- **Prevent the activated instrument from contacting hard objects, metal or plastic instruments. Otherwise, the tissue pad or blade may be damaged and the clamp arm may be cracked.**
- **When the instrument is activated and there is no tissue between the blade and tissue pad, keep the jaws open and do not apply pressure on it. Cutting in such situation may result in cracked tissue pad.**
- **The blade of the activated ultrasonic surgical instrument heats tissue by friction to cut or coagulate the tissue, which can result in high temperatures (>70°C) at jaws. Normal surgical operations do not pose a risk of burns. When the instrument is activated, make sure that the jaws and distal end of the shaft sleeve do not contact non-surgical sites, avoiding tissue burns.**
- **Long and continuous activations may cause the temperature on the tip of instrument increasing. To avoid burns, ensure adequate cooling between activations.**
- **If the ultrasonic surgical instrument or transducer generates any sharp sound, the transducer may be beyond its service life, or the ultrasonic surgical instrument is not properly connected. In this case, temperature of the shaft may rise, resulting in operator or patient injury.**
- **Do not modify the shape of the blade, for example, bend or sharpen the blade. This may cause blade malfunction and operator or patient injury.**
- **Do not open the jaws of the instrument while the instrument is passing through a trocar sleeve. Otherwise, instrument damage may result.**
- **To remove tissue on the ultrasonic surgical instrument, wipe the instrument with a moist gauze piece. Never use abrasives to clean the jaws. If there is still residual tissue, ensure that the instrument is not activated, and then remove it by using hemostats. To prevent the instrument from scratching or damage, do not allow the hemostats contacting the activated instrument.**
- **Make sure that the tip of active instrument do not contact non-surgical sites, avoiding tissue burns.**
- **In case surgical smoke obscures the visual field, use a smoke evacuator to clear the smoke.**
- **Do not touch the patient and live parts simultaneously.**
- **After removal of the instrument, check whether hemostasis of the tissue is adequate. If not, use proper methods to achieve hemostasis.**
- **This equipment contains no user serviceable parts. In case of any equipment failure, contact the service personnel.**
- **Mindray shall not be responsible for personal injury and equipment damage caused by maintenance attempts of service personnel not authorized by Mindray.**
- **The ultrasonic surgical instrument is pre-sterile and packaged for single use only. Therefore, dispose of any opened ultrasonic surgical instrument no matter whether it is used.**
- **Reuse and improper reprocessing of the ultrasonic surgical instrument may damage its structure or cause instrument failure.**
- **Reuse and improper reprocessing of the ultrasonic surgical instrument may cause patient infection, or pose a risk of contamination, resulting in patient injury, illness, or even death.**
- **Dispose of the package material as per the applicable waste control regulations. Keep the packing material out of children's reach.**

NOTE

- **Before the surgery, prepare a backup instrument to avoid surgery interruption due to possible device failure.**
- **If the activation is inadvertently stopped during sealing, keep the jaws closed before activating the instrument again. To ensure adequate hemostasis, do not release the trigger during sealing.**
- **To cut thick tissue, select a higher power level to achieve enough cutting speed. To coagulate blood for large areas of tissue, select a lower power level.**

1.3 Safety Specifications

The device is classified, according to IEC 60601-1:

Degree of protection against electrical shock	TYPE CF APPLIED PART when connected to the generator
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Installation type	Non-permanently installed equipment

1.4 Output Parameters

Reference primary tip vibration excursion	74 µm ± 35%
Primary acoustic output area	≤ 3mm^2
Drive frequency	55.5 kHz ± 1.5%
Derived output acoustic power	<5W
Type of frequency control of the system	Continuous automatic tuning
Power reserve index	>3

NOTE

- **The output parameters of all ultrasonic surgical instruments included in this product are the same.**

1.5 EMC

WARNING

- **The use of unapproved accessories may diminish instrument performance.**
- **Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of instrument.**
- **Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **Other devices may interfere with this equipment even though they meet the requirements of CISPR.**
- **Use of portable or mobile communications devices can degrade the performance of the equipment.**
- **This equipment is not intended for use in residential environments and can possibly not provide adequate protection to radio reception in such environments.**
- **This instrument is intended for use in professional healthcare environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**
- **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM, shielding the location or stopping using the ME EQUIPMENT or ME SYSTEM and contact the service personnel.**