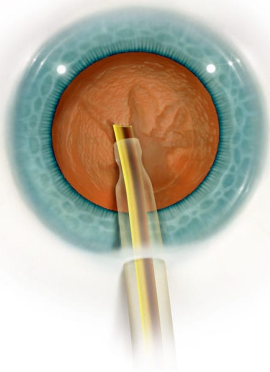


Identification

Description: MST Phaco Tips
Article Number: Multiple, See attached Declaration of Conformity
UMDNS Code: 17596 Cataract Extraction Units, Phacoemulsification



General Information

Intended Use: Phacoemulsification tips are used in conjunction with a phacoemulsification machine and handpiece to liquefy and aspirate lens material from the eye during cataract surgery.

Notified Body: Intertek

Certification: CE0413

European MD Classification: Class IIa according to Rule 6

Manufacturer: MicroSurgical Technology Inc. 8415 154th Ave NE, Redmond, WA 98052 USA

Technical Data

Type of Use: Reusable up to 20x & Single-Use

Sterilization: Gama Radiation/ Steam at point of use

Shelf Life: 3 years

Instructions for Use: 67-0003-01 Reusable Phaco Tips, 67-0088-01 Single-Use Phaco Tips

Packaging: Sterile barrier system: PETG tray with Tyvek lid

Protective packaging: cardboard box

Packaging Size: 1 cardboard box contains 12 trays

Content of Tray: 6 trays contain 1 tip, 1 wrench, 6 additional trays contain 1 or 2 sleeves

Material:	Phaco Tips:	Titanium
	Phaco Wrench:	Radel R-5000 NT
	Sleeve:	Silicone

PVC: No

Phthalates: No

Animal origin: No

Description of Models

						
Family Type	1.1mm Sharp	0.9mm Sharp	Packard 0.7mm Sharp	1.1mm Dewey	0.9mm Dewey	Packard 0.7mm Dewey
Dimensions	Tip: 0.931" Shaft OD: 0.0433"	Tip: 0.870" Shaft OD: 0.033"	Tip: 0.870" Shaft OD: 0.0225"	Tip: 0.870" Shaft OD: 0.0420"	Tip: 0.870" Shaft OD: 0.0280"	Tip: 0.870" Shaft OD: 0.0280"
						
Family Type	A1 1.1mm Sharp	A1 0.9mm Sharp	Packard A1 0.7mm Sharp	A1 1.1mm Dewey	A1 0.9mm Dewey	Packard A1 0.7mm Dewey
Dimensions	Tip: 1.210" Shaft OD: 0.0280"	Tip: 1.220" Shaft OD: 0.0225"	Tip: 1.195" Shaft OD: 0.0280"	Tip: 1.210" Shaft OD: 0.0280"	Tip: 1.220" Shaft OD: 0.0225"	Tip: 1.195" Shaft OD: 0.0280"

Note: The table above is a representation of what MST manufactures. Each tip is available in 0°, 15°, 30°, and 45° bevel angles as well as straight shaft, bent 12° or 20°. Incision sizes range from 1.8" to 2.85".

Attachment

Declaration of Conformity



DECLARATION OF CONFORMITY

We,

MicroSurgical Technology Inc.

8415 154th Ave NE

Redmond, WA 98052 USA

Ph: 425-556-0544

Fax: 425-556-0437

declare under our sole responsibility that the class IIa product(s) listed on the product list attachment to which this declaration relates is in conformity with the European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex II excluding (4), including the Swedish Medical Products Agency norms for the medical devices LVFS 2003:11 and the following standards or other normative documents

Standard ID	Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological Evaluation of medical devices – Part 5: Tests for cytotoxicity, invitro method
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 17664:2004	Sterilization of medical devices —Information to be provided by the manufacturer for the processing of resterilizable medical devices
EN ISO 17665-1:2006	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN 556-1:2001/AC 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose



Following the provisions of EC Directive 93 / 42 / EEC and all applicable amendments which apply to them, as stated in Annex II, Article 3 of this directive.

Certification for a Full Quality Assurance System:

Certificate N.: 41377505-00
Issued by: Intertek Semko AB
Torshamnsgatan 43
Box 1103
SE-164 22 Kista,
Sweden

Notified Body Number: 0413

The Technical File is maintained at:

MicroSurgical Technology Inc. 8415 154th Ave NE Redmond, WA 98052 USA

The authorized representative located within the Community is:

MDSS GmbH Schiffgraben 41 30175 Hannover, Germany Phone: +49 511 62628630
Fax: +49 511 62628633

This declaration shall be made available to national authorities for inspection for no less than 5 years after the last product has been manufactured.

Date of issue: August 17, 2018

Place of issue: Redmond, WA

A handwritten signature in blue ink that reads 'Cecil Chrisinger'.

Cecil Chrisinger

Manager Regulatory Affairs

MicroSurgical Technology Inc.



MST Phacoemulsification Tips

This product list belongs to the MST Phacoemulsification Tips Declaration of Conformity and specifies the CE-marked products concerned that MicroSurgical Technology Inc. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC, concerning medical devices. The following list identifies the products.

MST Phacoemulsification Tips	
Model	Brand Name
PT-21600	Phaco Tip MST 1.1mm A1 0deg Str.
PT-21615	Phaco Tip MST 1.1mm A1 15deg Str.
PT-21630	Phaco Tip MST 1.1mm A1 30deg Str.
PT-21645	Phaco Tip MST 1.1mm A1 45deg Str.
PT-21915	Phaco Tip MST 0.9mm Str. A1 15deg
PT-21930	Phaco Tip MST 0.9mm Str. A1 30deg
PT-22030	MST/Dewey .9mm A1 Phaco Tip 30deg
PT-22130	MST/Dewey .9mm A1 Bent Ph Tip 30deg
PT-22145	MST/Dewey .9mm A1 Bent Ph Tip 45deg
PT-22215	MST/Dewey 1.1mm A1 Phaco Tip 15deg
PT-22245	MST/Dewey 1.1mm A1 Phaco Tip 45deg
PT-22830	MST/Dewey Mini A1 Ph Tip 30deg
PT-26530	Phaco Tip, MST X1, .9mm, 30°
PT-27230	Phaco Tip MST .9mm 30 Deg Bent
PT-27245	Phaco Tip MST .9mm 45 Deg Bent
PT-27300	MST/Dewey Phaco Tip 0deg 20g
PT-27315	MST/Dewey Phaco Tip 15deg 20g
PT-27330	MST/Dewey Phaco Tip 30deg 20g
PT-27345	MST/Dewey Phaco Tip 45deg 20g
PT-27400	MST/Dewey .9mm Ph Tip 0deg Bent
PT-27430	MST/Dewey .9mm Ph Tip 30deg Bent
PT-27445	MST/Dewey .9mm Ph Tip 45deg Bent
PT-27600	Phaco Tip MST 1.1mm 0 Deg Straight
PT-27615	Phaco Tip MST 1.1mm 15 Deg Straight
PT-27630	Phaco Tip MST 1.1mm 30° Straight
PT-27645	Phaco Tip MST 1.1mm 45 Deg Straight
PT-27730	Phaco Tip MST 1.1mm 30° Bent
PT-27900	Phaco Tip MST .9mm 0 Deg Straight
PT-27915	Phaco Tip MST .9mm 15 Deg Straight
PT-27930	Phaco Tip MST .9mm 30 Deg Straight
PT-28200	MST/Dewey 1.1mm Ph Tip 0deg Str
PT-28215	MST/Dewey 1.1mm Ph Tip 15deg Str
PT-28230	MST/Dewey 1.1mm Ph Tip 30deg Str
PT-28330	MST/Dewey 1.1mm Ph Tip 30deg Bent
PT-29830	MST/Dewey Mini Ph Tip 30deg
PT-30630	MST/Dewey Mini S2 Ph Tip 30deg
PT-30830	MST Mini S2 Phaco Tip 30 Deg
PT-30845	MST Mini S2 Phaco Tip 45 Deg
PT-30930-P	MST/Dewey 0.9mm Mini A1 Bent Ph Tip 30deg
PT-30930-R	MST/Dewey 0.9mm Mini A1 Bent Ph Tip 30deg
PT-30945-P	MST/Dewey 0.9mm Mini A1 Bent Ph Tip 45deg
PT-30945-R	MST/Dewey 0.9mm Mini A1 Bent Ph Tip 45deg
PT-31030	MST/Dewey 0.9mm Taper A1 Bent Ph Tip 30deg
PT-31045	MST/Dewey 0.9mm Taper A1 Bent Ph Tip 45deg
PT-31140	MST 0.9mm A1 Bent Phaco Tip Reverse Bevel
PT-31240-P	MST/Dewey .9 Mini A1 12deg Bent Phaco Tip

MST Phacoemulsification Tips	
Model	Brand Name
PT-31240-R	MST/Dewey .9 Mini A1 12deg Bent Phaco Tip
PT-31340	MST/Herman II 1.1mm Phaco Tip
PT-31430-P	MST 0.9 Mini A1 Bent Phaco Tip
PT-31430-R	MST 0.9 Mini A1 Bent Phaco Tip
PT-31445-P	MST 0.9 Mini A1 Bent Phaco Tip
PT-31445-R	MST 0.9 Mini A1 Bent Phaco Tip
PT-31530	MST 0.9mm Taper A1 Bent Phaco Tip 30deg
PT-31545	MST 0.9mm Taper A1 Bent Phaco Tip 45deg
PT-31640-P	MST 0.9 Mini A1 12deg Bent Phaco Tip Reverse Bevel
PT-31640-R	MST 0.9 Mini A1 12deg Bent Phaco Tip Reverse Bevel
PT-31730-G	MST 0.7mm A1 Bent Phaco Tip 30 deg
PT-31730-P	MST 0.7mm A1 Bent Phaco Tip 30 deg
PT-31730-R	MST 0.7mm A1 Bent Phaco Tip 30 deg
PT-31745-G	MST 0.7mm A1 Bent Phaco Tip 45 deg
PT-31745-P	MST 0.7mm A1 Bent Phaco Tip 45 deg
PT-31745-R	MST 0.7mm A1 Bent Phaco Tip 45 deg
PT-31830	MST 0.7mm Bent Phaco Tip 30 deg
PT-31830-B	MST 0.7mm Bent Phaco Tip 30 deg
PT-31830-GRN	MST 0.7mm Bent Phaco Tip 30 deg
PT-31830-Y	MST 0.7mm Bent Phaco Tip 30 deg
PT-31845-B	MST/Packard .7mm Bent Phaco Tip 45 deg
PT-31845-G	MST/Packard .7mm Bent Phaco Tip 45 deg
PT-31845-Y	MST/Packard .7mm Bent Phaco Tip 45 deg
PT-32030-P	MST/Dewey .9mm Mini A1 12deg Bent 30 Deg Bevel Phaco Tip
PT-32030-R	MST/Dewey .9mm Mini A1 12deg Bent 30 Deg Bevel Phaco Tip
PT-32045-P	MST/Dewey .9mm Mini A1 12deg Bent 45 Deg Bevel Phaco Tip
PT-32045-R	MST/Dewey .9mm Mini A1 12deg Bent 45 Deg Bevel Phaco Tip
PT-32130-P	MST .9mm Mini A1 12deg Bent 30 Deg Bevel Phaco Tip
PT-32130-R	MST .9mm Mini A1 12deg Bent 30 Deg Bevel Phaco Tip
PT-32145-P	MST .9mm Mini A1 12deg Bent 45 Deg Bevel Phaco Tip
PT-32145-R	MST .9mm Mini A1 12deg Bent 45 Deg Bevel Phaco Tip
PT-32230-G	MST/Packard A1 .7mm 12deg Bent Phaco Tip, 30 deg
PT-32230-P	MST/Packard A1 .7mm 12deg Bent Phaco Tip, 30 deg
PT-32230-R	MST/Packard A1 .7mm 12deg Bent Phaco Tip, 30 deg
PT-32245-G	MST/Packard A1 .7mm 12deg Bend Phaco Tip, 45deg
PT-32245-P	MST/Packard A1 .7mm 12deg Bend Phaco Tip, 45deg
PT-32245-R	MST/Packard A1 .7mm 12deg Bend Phaco Tip, 45deg
PT-32315	MST/Packard .7mm Straight Phaco Tip 15deg
PT-32315-B	MST/Packard .7mm Straight Phaco Tip 15°
PT-32315-Y	MST/Packard .7mm Straight Phaco Tip 15°
PT-32330	MST/Packard .7mm Straight Phaco Tip 30°
PT-32330-B	MST/Packard .7mm Straight Phaco Tip 30°
PT-32330-GRN	MST/Packard .7mm Straight Phaco Tip 30°
PT-32330-Y	MST/Packard .7mm Straight Phaco Tip 30°
PT-32345-B	MST/Packard .7mm straight Phaco tip 45°
PT-32345-G	MST/Packard .7mm straight Phaco tip 45°
PT-32345-Y	MST/Packard .7mm straight Phaco tip 45°
PT-32430	MST/Packard .7mm Straight Phaco Tip Dewey 30°
PT-32430-B	MST/Packard .7mm Straight Phaco Tip Dewey 30°
PT-32430-GRN	MST/Packard .7mm Straight Phaco Tip Dewey 30°
PT-32430-Y	MST/Packard .7mm Straight Phaco Tip Dewey 30°
PT-32445-B	MST/Packard .7mm Straight Phaco tip Dewey 45°
PT-32445-G	MST/Packard .7mm Straight Phaco tip Dewey 45°
PT-32445-Y	MST/Packard .7mm Straight Phaco tip Dewey 45°



MST Phacoemulsification Tips	
Model	Brand Name
PT-32530	MST/Packard .7mm Bent Phaco Tip Dewey 30°
PT-32530-B	MST/Packard .7mm Bent Phaco Tip Dewey 30°
PT-32530-GRN	MST/Packard .7mm Bent Phaco Tip Dewey 30°
PT-32530-Y	MST/Packard .7mm Bent Phaco Tip Dewey 30°
PT-32545-B	MST/Packard .7mm bent phaco tip Dewey 45°
PT-32545-G	MST/Packard .7mm bent phaco tip Dewey 45°
PT-32545-Y	MST/Packard .7mm bent phaco tip Dewey 45°
PT-32630	MST/Packard .7mm Bent Phaco Tip Reverse Bevel
PT-32630-B	MST/Packard .7mm Bent Phaco Tip Reverse Bevel
PT-32630-Y	MST/Packard .7mm Bent Phaco Tip Reverse Bevel
PT-32730	MST/Packard .7mm Bent Phaco Tip Dewey Reverse Bevel
PT-32730-B	MST/Packard .7mm Bent Phaco Tip Dewey Reverse Bevel
PT-32730-Y	MST/Packard .7mm Bent Phaco Tip Dewey Reverse Bevel
PT-32830	MST Mini Phaco Tip, 30° bevel
PT-32845	MST Mini Phaco Tip, 45° bevel
PT-32930-G	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 30°
PT-32930-P	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 30°
PT-32930-R	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 30°
PT-32945-G	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 45°
PT-32945-P	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 45°
PT-32945-R	MST/Packard A1 .7mm 12° Bend Phaco Tip Dewey 45°
PT-33030-G	MST/Packard A1 .7mm 12°Bend Phaco Tip, Reverse Bevel
PT-33030-P	MST/Packard A1 .7mm 12°Bend Phaco Tip, Reverse Bevel
PT-33030-R	MST/Packard A1 .7mm 12°Bend Phaco Tip, Reverse Bevel
PT-33130-G	MST/Packard A1 .7mm 12°Bend Phaco Tip Dewey, Reverse Bevel
PT-33130-P	MST/Packard A1 .7mm 12°Bend Phaco Tip Dewey, Reverse Bevel
PT-33130-R	MST/Packard A1 .7mm 12°Bend Phaco Tip Dewey, Reverse Bevel
PT-33230-G	MST/Packard A1 .7mm Phaco Tip
PT-33230-P	MST/Packard A1 .7mm Phaco Tip
PT-33230-R	MST/Packard A1 .7mm Phaco Tip
PT-33245-G	MST/Packard A1 .7mm ph tip Bent Dewey 45°
PT-33245-P	MST/Packard A1 .7mm ph tip Bent Dewey 45°
PT-33245-R	MST/Packard A1 .7mm ph tip Bent Dewey 45°
PT-33330-G	MST/Packard A1 .7mm Phaco Tip, Reverse Bevel Bent
PT-33330-P	MST/Packard A1 .7mm Phaco Tip, Reverse Bevel Bent
PT-33330-R	MST/Packard A1 .7mm Phaco Tip, Reverse Bevel Bent
PT-33430-G	MST/Packard A1 .7mm Phaco Tip Bent Dewey Reverse Bevel
PT-33430-P	MST/Packard A1 .7mm Phaco Tip Bent Dewey Reverse Bevel
PT-33430-R	MST/Packard A1 .7mm Phaco Tip Bent Dewey Reverse Bevel
PT-34130	MST A1 0.9 Straight Phaco Tip, 30° Bevel
PT-34230	MST A1 0.9 Straight Phaco Tip, Dewey 30° Bevel
PT-34430	MST A1 0.9 20° Bent Phaco Tip, Dewey 30° Bevel
PT-34445	MST A1 0.9 20° Bent Phaco Tip, Dewey 45° Bevel
PT-35030-R	MST/Sonata Tip 0.7mm rvs bevel
PT-36030-GRN	MST/Sonata Tip 0.7mm rvs bevel
PT-36030-Y	MST/Sonata Tip 0.7mm rvs bevel
TW-20001	MST 4 Flat Phaco Tip Wrench Metal