



PHYSICIENT
SMARTER INSTRUMENTS FOR SURGEONS™

Instructions For Use

Differential Dissector

REF 2500



Manufactured by:

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Physcient Differential Dissector

REF 2500

Intended Use

The Physcient Differential Dissector is intended for blunt dissection during plastic and open general surgical procedures. The device is sold sterile and is for single-use only. It may not be re-processed or re-sterilized.

Contraindications

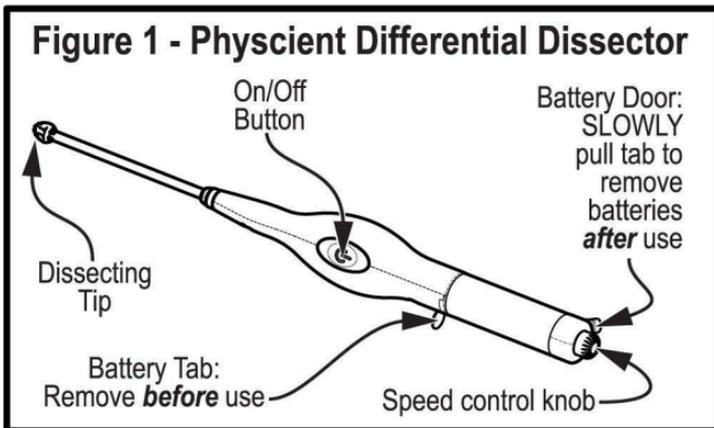
DO NOT use in intra-cardiac, intra-vascular, or central nervous system procedures. Safe and effective use of the device in these procedures has not been validated.

DO NOT use on tissue where malignancy or infection is expected. The device may spread tumor cells or infectious agents.

DO NOT use on tissue made fragile by steroids, radiation, or other agents.

Device Description

The Physcient Differential Dissector [Figure 1] is a hand-held, motorized, blunt dissection tool for use by surgeons in plastic surgery and open general surgical procedures such as thoracic, gastrointestinal, gynecological, urological, peripheral vascular, and orthopedic. It uses a small, battery-powered motor to oscillate a proprietary tip that aids in blunt dissection. The speed of the tip can be adjusted using the speed control knob. The Differential Dissector is shipped pre-sterilized. The Differential Dissector is designed for a single-use after which the batteries should be removed and the device disposed of as biohazardous waste.



Principles of Use

The Physcient Differential Dissector is a hand-held instrument used for blunt dissection of tissues during surgery. The device uses a small motor to oscillate a dissecting tip at the end of its shaft. The device has two controls: an On/Off button on the side of the handle, and a speed control knob on the end of the handle.

(Principles of Use continued on next page)

Principles of Use (continued)

The oscillating tip of the Differential Dissector is held against the tissue to be dissected. The device differentially disrupts softer tissues (e.g. mesenteries and fatty tissues) composed of few organized fibers. Conversely, the device has a greatly reduced effect on firmer tissues (e.g. blood vessel walls, nerve fibers, organ capsules) that are composed of densely packed, organized arrays of collagen fibers. The result is that when the device is pushed into a tissue comprised of *both* softer *and* firmer tissues, the softer tissues are disrupted while the firmer tissues are relatively unaffected. Disruption is mechanical: there is no heat, electricity, or other form of energy used. Throughout its use, the surgeon controls dissection of tissues by varying the force of application, the speed of oscillation, the orientation of the tip, the point of application, and the use of counter-traction. The device dissects more rapidly (and the risk of accidentally damaging a critical tissue is greater) when the force is greater, the speed is faster, and the counter-traction more greatly strains tissue at the point of application of the tip of the device.

Warnings

DO NOT use a device if:

- the outer packaging appears severely damaged,
- it is past the expiration date,
- the sterile package appears compromised,
- the device appears damaged,
- the device is dropped or subjected to a hard impact,
- the dissection tip is nicked, cracked, or has a sharp edge,

harm/contamination of the patient and/or damage to the product can occur.

DO NOT re-use the device - it is for single use only. Reuse or resterilization could result in contamination of patient and/or damage to the product.

DO NOT reprocess or re-sterilize the device. No attempt should be made to clean, resterilize or reuse this device. Contamination of patient and/or damage to the product can occur.

DO NOT modify this device or use it if it has been modified. It may not perform as intended.

DO NOT use if the tip does not move when the device is turned on, or if turning the speed to a higher setting does not move the tip. Turn off the device and discard it, and open another.

DO NOT use the device in an oxygen-rich environment. This may cause fire.

DO NOT operate the device with a duty cycle beyond 1 minute on and 1 minute off, as the temperature of the device may exceed 41°C.

DO NOT apply the tip continuously to the same spot on delicate tissue, organs, or vessels for longer than 30 seconds, as tissue damage due to heat may occur. It may irritate or damage these tissues.

DO NOT apply excessive force to the tip or handle during use. Damage to the device can occur.

(Warnings continued on next page)

Warnings (continued)

DO NOT push the Differential Dissector into the interior apex of acute bifurcations in branching structures [Figure 5]. The tip may cause avulsion of a side branch of a vessel or nerve.

DO NOT use if the speed of the device increases unexpectedly or the speed control knob does not change the speed. Turn off the device, discard it, and use another one.

DO NOT submerge the device in a liquid or try to clean the device after use. It should be disposed of properly as biohazardous waste. Reuse or reesterilization could result in contamination of patient and/or damage to the product.

DO NOT press the moving tip against staples. The staples may be dislodged, or the staples may damage the tip.

To avoid possible vibration-related injury to the operator, **DO NOT** run the Differential Dissectors for more than two hours cumulative in any eight-hour period.

For some sensitive instruments, the Differential Dissector may cause electrical interference. If this occurs, move the instrument away from the Differential Dissector or discontinue using the dissector.

Precautions

When approaching critical anatomy, move slowly through the tissue so critical structures are not accidentally damaged.

If resistance is felt during dissection, investigate the area before continuing. There may be a vessel or fibrous tissue constraining the motion of the Differential Dissector that must be addressed.

When working directly below the skin, be careful not to apply too much upward force which can puncture the skin.

Turn off the device when not in use.

Expected Adverse Events from Dissection (alphabetic)

- Allergic response
- Bleeding
- Bruising
- Erythema
- Hematoma
- Impetigo
- Infection
- Necrosis
- Numbness, tingling, or some loss of feeling
- Pain at the site
- Seroma
- Skin contour irregularities
- Swelling of the distal extremities
- Thrombosis
- Any of the known complications from oral medications
- Any of the known complications from tumescent solution

Observed Adverse Events Caused by the device (decreasing order of frequency)

- Superficial vein thrombosis
- Seroma
- Erythema
- Impetigo

Packaging

The Physcient Differential Dissector is individually packaged and sterilized with ethylene oxide (EtO). It contains batteries that are fully charged and is ready for use.

Storage

Store the device in the original packaging in a controlled storage area, temperature: -20°C to +60°C; humidity: 30% to 85%; atmospheric pressure: 50 kPa to 106 kPa.

Use Conditions

Temperature: +15°C to +25°C (+59°F to +77°F); humidity: 30-70% non-condensing; atmospheric pressure: 70 kPa to 106 kPa.

Component Materials [patient-contacting]

All patient-contacting materials of the Physcient Differential Dissector are known to be biocompatible and non-toxic for the intended use.

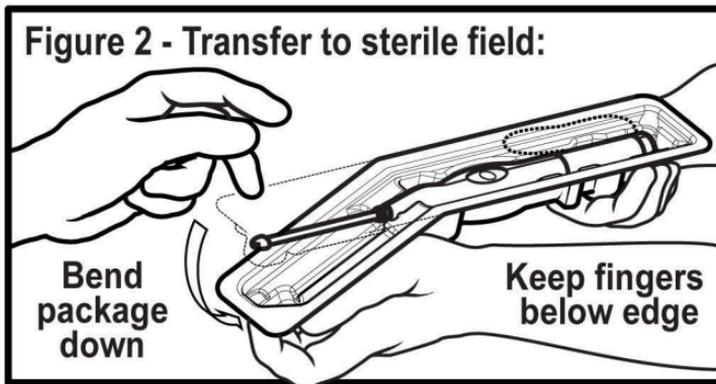
- PEEK (polyether ether ketone)
- Stainless steel
- PEBA (polyether block amide) as the cable coating
- Biocompatible silicone oil (polydimethylsiloxane)
- Silicone rubber

Materials Provided

One Differential Dissector.

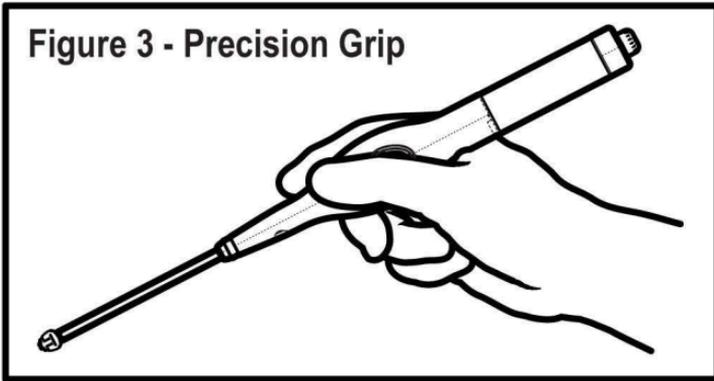
Device Preparation

1. Remove the outer packaging.
2. Transfer the device to the sterile field: peel the top from the sterile package, then bend the tray as shown, then allow a user with sterile, gloved hands to remove the device from its tray [Figure 2].



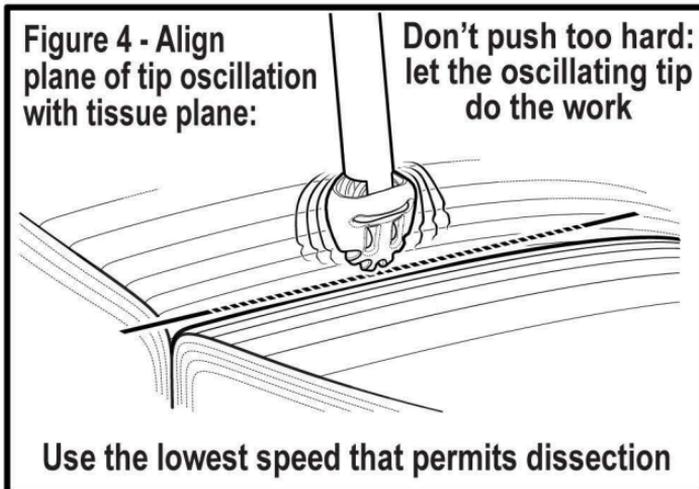
3. Remove the yellow battery tab, and discard it safely.
4. Press the power button to verify that the device turns on: the blue lights will turn on, and the tip will oscillate.
5. Rotate the speed control knob to verify that the tip speed changes. *If it does not change, discard the device and open another.*
6. Press the power button to turn the device off.

Figure 3 - Precision Grip



Device Use Instructions

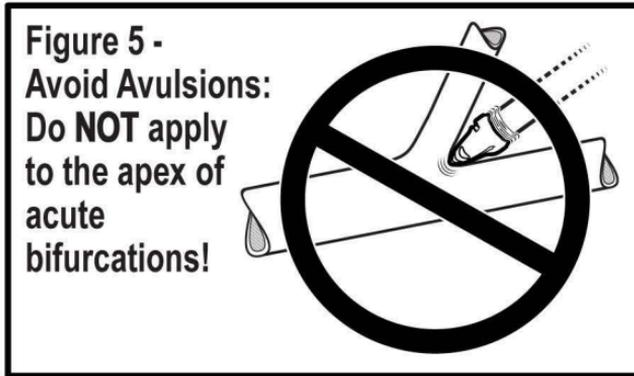
1. The device can be held with a precision grip [Figure 3].
2. To turn on the device, press the power button. Turn off the device by pressing the power button again.
3. The speed of the tip can be controlled by turning the speed control knob on the back of the device. Turn clockwise to increase the speed, and counter-clockwise to decrease the speed.
4. When first starting a dissection, use lower speeds and increase speed only if more aggressive dissection is desired.
5. The device can be rotated in the hand to change the orientation of the tip to match the tissue's structure. The tip's plane of oscillation should be aligned in parallel with the tissue plane being dissected [Figure 4].
6. To increase the aggressiveness of dissection, increase speed of dissector, increase force of application, or use more counter-traction.



(Device Use Instructions continued on next page)

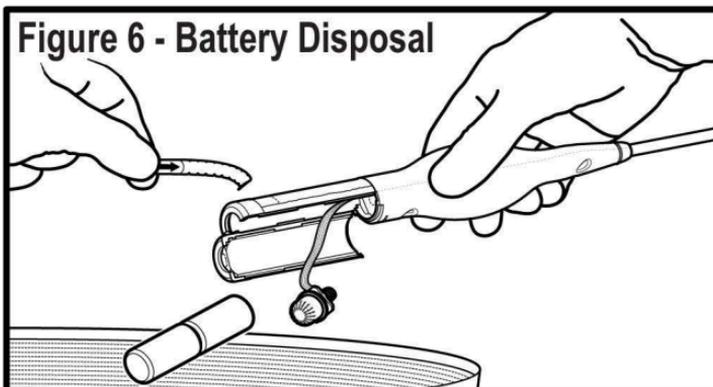
Device Use Instructions (continued)

- When approaching critical anatomy, move slowly through the tissue so that critical structures are not accidentally damaged. Do not push the Differential Dissector into the interior apex of acute bifurcations of branching structures [Figure 5]. The tip may cause avulsion of a side branch of a vessel or nerve.



- If tissue appears to bind to the tip of the device, the area being dissected can be lubricated with a sterile saline or surgical lubricant. This reduces friction during dissection.
- If resistance is felt during dissection, investigate the area before continuing. There may be a vessel or fibrous tissue that needs to be addressed.
- When working directly below the skin, be careful not to apply too much upward force which can puncture the skin.
- The device is designed for about one hour of typical use. If the device stops working, it may be that the batteries are drained. Dispose of the device and use another one.
- Once the procedure is completed, the batteries can be removed before disposal of the device. To remove the batteries, slowly tear the perforated label on the back of the device, then open the battery door to access the batteries [Figure 6]. Dispose of the batteries in your facility's battery collection center, if available. Dispose of the remainder of the device in the biohazard collection center.

Do not reprocess or re-sterilize the device.



The DD1 Differential Dissector needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below. The specification tables below are for the DD1 per IEC 60601-1-2.

Portable and mobile RF communications equipment can affect the DD1 Differential Dissector.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The DD1 is intended for use in the electromagnetic environment specified below. The customer or user of the DD1 should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The DD1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	
Harmonics IEC 61000-3-2	N/A	Battery powered
Flicker IEC 61000-3-3	N/A	Battery powered
		The DD1 is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Caution: The DD1 Differential Dissector should not be used adjacent to other equipment. If adjacent use is necessary, the DD1 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The DD1 is intended for use in the electromagnetic environment specified below. The customer or user of the DD1 should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	N/A	Battery powered
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	N/A	Battery powered
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 cycle 60% Dip for 5 cycles 30% Dip for 25 cycles >95% Dip for 5 seconds	N/A	Battery powered
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (cont.)

The DD1 is intended for use in the electromagnetic environment specified below. The customer or user of the DD1 should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>N/A (battery powered and no I/O lines)</p> <p>(E1) = 3 V/m</p>	<p>Portable and mobile communications equipment should be separated from the DD1 by no less than the distances calculated/listed below:</p> <p>$D = (3.5/V1)(\text{Sqrt } P)$ 150 kHz to 80 MHz</p> <p>$D = (3.5/E1)(\text{Sqrt } P)$ 80 MHz to 800 MHz</p> <p>$D = (7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz</p> <p>where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

Recommended Separations Distances for the DD1

The DD1 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the DD1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the DD1 as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz	Separation (m) 80 MHz to 800 MHz	Separation (m) 800 MHz to 2.5 GHz
	$D = (3.5/V1)(\text{Sqrt } P)$	$D = (3.5/E1)(\text{Sqrt } P)$	$D = (7/E1)(\text{Sqrt } P)$
0.01	N/A	0.12	0.24
0.1	N/A	0.37	0.74
1	N/A	1.2	2.4
10	N/A	3.7	7.4
100	N/A	12	24

Troubleshooting

Problem	Solution
Device does not turn on	<p>Make sure that the yellow battery tab was removed from the device.</p> <p>Turn the speed control knob clockwise to increase the speed, and then press the power button again.</p> <p>If the blue lights in the On/Off switch are on, but the tip is not moving, do not use that device. Turn off that device, dispose of it, and open a new one.</p>
Device does not turn off	<p>Carefully remove the device from the patient, then remove the batteries to stop the device. To remove the batteries, SLOWLY tear the perforated label on the back of the device. Dispose of that device and use another one.</p>
Speed too slow	<p>Turn the speed control knob clockwise (to the right) as shown by the indicator on the device.</p>
Speed too fast	<p>Turn the speed control knob counter-clockwise (to the left) as shown by the indicator on the device.</p> <p>If the speed control knob does not change the device's speed, turn off that device, dispose of it, and use another.</p>
Tissue adheres to the tip	<p>If tissue appears to bind to the tip of the device (especially if the tissue appears to be dry) wipe the tip with a sterile gauze or cloth.</p> <p>The area being dissected can be lubricated with sterile saline or surgical lubricant. This reduces friction during surgery and promotes dissection.</p>
Tip breaks	<p>Turn off the device, then remove the tip or tip fragments from patient. Dispose of the device.</p>

REF

Catalog number. Reference number. Reorder number.

LOT

Batch code. Lot number. Batch number.



Use by date.



Consult instructions for use.



Caution, consult accompanying documents.



Manufacturer.



Date of manufacture.



Single use. Do not reuse.



Do not use if package is damaged.



Does not contain natural rubber latex.



Do not resterilize.

STERILE EO

Sterilized using ethylene oxide.



Applied part, Type CF



Temperature limitations.



Atmospheric pressure limitations.



Humidity limitations.