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Section K : Summary of Safety and Effectiveness

Invitro and exvivo testing was conducted to establish equivalence to predicate devices in terms of safety and efficacy and to characterize the performance of the laser system using different types of fiber optics.

When used as a general surgical instrument, the laser is able to provide power to cut or coagulate tissues. The table below shows the penetration depth in porcine tissues (invitro) as a function of time and exposure to diode laser power. Penetration depths for other types of tissues are not presented in the table below, however tissues with similar coloration will result in similar penetration depths. For gynecological application in which it is desired to treat highly vascular endometrial tissue, liver can be used as a reference.

Exposure	Penetration Depth (mm)		
Power/Time	Liver	Kidney	Heart
5 Watts / 1 sec	1.73±0.20	1.75±0.34	1.77±0.37
5 Watts / 2 sec	2.48±0.73	2.29±0.31	2.19±0.62
5 Watts / 5 sec	3.37±0.64	3.31±0.39	3.03±0.72
10 Watts / 1 sec	2.26±0.47	1.90±0.35	2.25±0.62
10 Watts / 2 sec	3.30±0.59	2.36±0.27	2.16±0.35
10 Watts / 5 sec	4.34±0.78	3.65±0.54	2.89±0.34
15 Watts / 1 sec	2.35±0.45	2.60±0.35	2.16±0.32
15 Watts / 2 sec	3.61±0.50	3.17±0.38	2.58±0.34
20 Watts / 1 sec	2.99±0.48	2.64±0.50	1.99±0.36
20 Watts / 2 sec	3.27±1.34	2.98±0.77	3.48±0.79
25 Watts / 1 sec	2.81±1.13	2.24±0.53	2.96±0.83
25 Watts / 2 sec	3.65±0.72	3.17±1.04	2.81±0.44

When used as a coagulating device, the Índigo laser in conjunction with a diffusing fiberoptic provides interstitial laser coagulation. The process of interstitial laser coagulation relies on quickly elevating tissue to a temperature range (Appox. 60 to 100°C) where tissue necrosis rapidly occurs, but below temperatures at which carbonization begins. Lesion sizes vary according to diffuser length and variation of tissue conditions.