

Orthopedic Drill Bits


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Material specifications and characteristics

Emerge uses only proven materials that have an extensive history of use for medical device cutting instruments. Emurge makes every effort to match the alloy of its bits and cutting instruments to that of the predicate device to ensure surgeon satisfaction and clinical equivalence.

All Emurge cutting instruments are made from alloys that are harder and stronger than the alloys used in implants. Alternative vendor bits that are made of implant grade metals have significant differences in strength and wear characteristics that can result in more rapid dulling. Emurge recognizes this as an issue and takes every precaution to ensure the highest quality and cutting capability.

Characteristic			Competitor 1 Predicate	Competitor 2 Alternative Mfg
Material	455 Stainless Steel	440A Stainless Steel	440A Stainless Steel	316LVM
Description	High strength / High hardness medical instrument grade stainless steel	High hardness medical instrument grade stainless steel	High hardness medical instrument grade stainless steel	High strength medical implant grade stainless steel
Standard	ASTM A-564	ASTM A-276	ASTM A-276	ASTM F-138
Hardness	HRC 47 - 55	HRC 47 - 55	HRC 50	HRC 32
Ultimate Tensile Strength	1724 MPa	1750 MPa	1750 MPa	1100 MPa
Elongation	10.0%	4.0%	4.0%	12.0%

Characteristic Descriptions

Hardness – Measures the material's wear resistance. The higher the value the slower the material will wear or, in the instance of a cutting instrument, the slower it will dull.

Ultimate Tensile Strength – Measures the material's resistance to deformation and failure. The higher the tensile strength value, the higher stress the material can withstand prior to failure.

Elongation – Relates to the material's tendency for deformation. The lower the elongation value, the less likely the material deforms under stress.