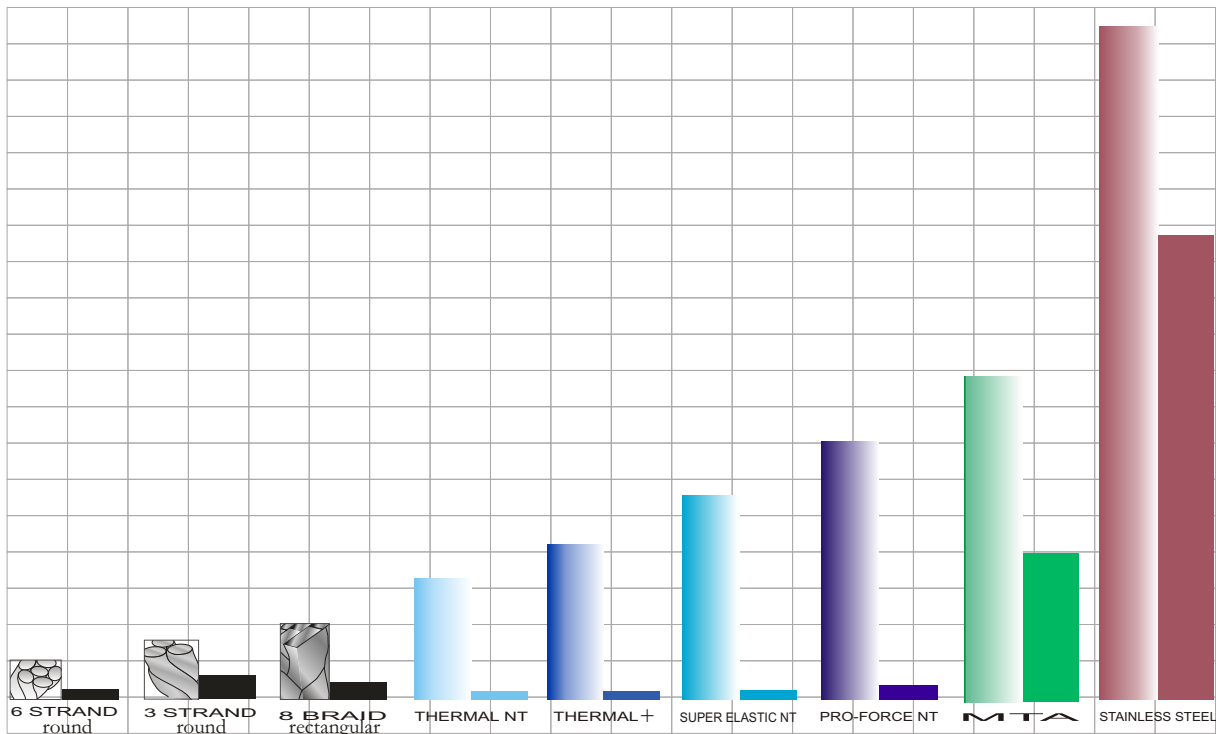


Phoenix Orthodontics wire products are certified to the highest levels of ISO 13485 (Quality Management System for Medical Devices) and incorporate full compliance requirements with CE Marking and the FDA QSR. Our orthodontic products conform to the provisions of the European Medical Device Directive (93/42/EEC), Annex II, for full quality assurance system. In addition, Phoenix Orthodontics, Inc. is FDA registered and all Phoenix manufacturers adhere to Quality Systems Regulations (Good Manufacturing Practices) as prescribed in the Code of Federal Regulations.



RELATIVE FORCE AND DEFORMATION CHART

MANUFACTURING OVERVIEW

STAINLESS STEEL:

All Phoenix stainless steel archwires are manufactured from 304VAR (Vacuum Air Remelted) material. 304 VAR stainless steel yields more uniform chemistry with minimal voids and contaminant. This process greatly reduces brittleness which may lead to breakage.

Functional testing is conducted to ensure highly reliable archwire of consistent high quality. Exacting wire tolerances are maintained throughout manufacture. Tight corner radii on Phoenix square and rectangular wire prevents spinning or slippage of wire in bracket slots. Strict flatness, tensile strength, and midline/posterior torque requirements on all archwire. No excessive torque (+3 degrees) guaranteed.

NICKEL TITANIUM:

All Phoenix nickel titanium archwires are rigidly inspected for product assurance. To assure optimum performance of our nickel titanium archwire, test methods are employed to identify forces and efficiency during the loading (engagement) and unloading (working) phases. When our archwire is engaged in the bracket, it exerts a “working” force to align the teeth and remove the offset between the brackets. To simulate actual use, our quality assurance department uses a three point bend test method. This testing accurately verifies the engagement and working forces of the nickel titanium arches.

The test measures the two forces; the force required to deform the archwire to a specified distance, and the force the wire exerts to return to its original shape. Our goal is to offer high efficiency archwire that not only offers more comfort to the patient but reduces valuable chair time.

