



**Instructions for Use: IFU Form 001**

**Orthodontic Archwires/Wires**

**Manufacturer Name & Address**

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### **Intended Use**

The product is intended to be used in conjunction with other orthodontic products, brackets, bands, tubes, springs, auxiliaries, elastomers, etc. to align, level, torque and tip in order to provide proper arch form for maloccluded and misaligned teeth. Orthodontic archwires are positioned within brackets and apply force to move teeth to the desired position, with the aid of above mentioned additional orthodontic products. The device is used by a trained professional. The professional decides whether the archwire is installed properly, based on their professional training and experience.

### **Use Indication**

Beta III CNA, NiTi, and Stainless Steel Orthodontic Wires are indicated for use on children and adults to correct dental malocclusions classified as Class I, II, and III and disturbances to bone and tooth growth, such as deep bite, open bite, crowded teeth, anterior crossbite, and posterior crossbite. The devices are typically in contact with the oral mucosa for greater than 30 days. Treatment is advised for patients with good oral health, including healthy gums and bone structure.

- The devices will be used by a qualified and trained orthodontic professionals, who will determine the best combination of devices suitable for individual patient prescriptions.
- This device is for single use only and is labeled as such.
- The devices are not intended to be life-sustaining or life supporting. The devices are not intended for newborn or infant use (0-1 year of age).

### **Description of the Device**

The product is intended to be used in conjunction with other orthodontic products, brackets, bands, tubes, springs, auxiliaries, elastomers, etc. to align, level, torque and tip in order to provide proper arch form for maloccluded and crooked teeth. Orthodontic archwires are positioned within brackets and apply force to move teeth to the desired position, with the aid of above mentioned additional orthodontic products.

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The intended patient population is pediatric and adult patients with primary, transitional, adolescent, or adult dentition.

Orthodontic wires are used by orthodontic professionals in the prescription for teeth alignment. This device is not sold as sterilized and does not require sterilization before use. The devices are based on existing well-established orthodontic fixed appliance treatment technologies and are intended to correct dental malocclusions and crooked teeth in children and adult populations. Orthodontic archwires are formed into wire shapes for typical anatomy of a patient's mouth. The orthodontic wires

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that Ultimate Wireforms offers are composed of Beta III Titanium, Nickel Titanium, and Stainless Steel materials sold in a variety of round, rectangular and square wire sizes. Orthodontic wires work by being tied/ligated into an orthodontic bracket system. The wire is deflected when tied to maligned teeth utilizing an orthodontic bracket system. The deflection of the wire causes a force to be applied to the tooth. The force from the wire deflection moves the tooth in a desired direction to align the teeth during orthodontic treatment.







These devices do not incorporate any medicinal, blood or any other human, or animal components. Treatment using a fixed orthodontic appliance is contraindicated in patients with the following;

- Precarious oral hygiene.
- Incapability of cooperating with treatment.
- An allergy to any of the device materials.
- Pre-existing conditions that may hinder orthodontic treatment.
- Pre-existing bone resorption.
- Existing decalcification of tooth enamel.

### Warnings and Precautions

All forms of medical and dental treatment, including orthodontics, involve some risks and/or limitations. Fortunately, in orthodontics, serious complications are infrequent. During orthodontic treatment, the orthodontist should disclose potential risks to the patient. Due to the length of orthodontic treatment, conditions may arise which are coincident but not caused by orthodontic treatment, such as tooth decay or permanent markings (decalcification).







### General Warnings

Warning	Description
	For single use only. Do not reuse
	Device is supplied in a non-sterile condition.
	Device contains nickel and may cause allergic reactions in nickel sensitive patients. Note: this warning does not pertain to orthodontic archwires/wires that are manufactured from Beta Titanium
	Patient may encounter discomfort via oral mucosa (tissue) irritation and pain during orthodontic treatment.
	Orthodontic wires or accessories may cause injury if accidentally ingested or aspirated. Immediately seek medical attention if orthodontic devices are ingested or aspirated.
	Ultimate Wireforms Orthodontic Wire Devices have not been evaluated for compatibility in an MRI environment. The MRI technician, radiological staff or your doctor should always be notified before any MRI procedure is conducted so that the proper actions can be taken.







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Warning	Description
	Stainless Steel wires are minimally magnetic and may cause concern for dislodgement or image artifacts.

### General Cautions

Caution	Description
	Practice good oral hygiene to prevent plaque build-up and potential subsequent periodontal disease.
	Patients should use a mouthguard while engaging in sports activities; injuries may occur or damages to the orthodontic devices.
	Care should be taken to avoid foods or patient habits that may be detrimental to the device. Follow recommendations from the orthodontist for proper care.
	The root lengths of teeth may become shortened during treatment. This may be of no clinical significance. In some cases, shortened roots may be a pre-existing condition.
	Tooth decay or permanent markings (demineralization) may occur during orthodontic treatment.
	Orthodontic wire devices may cause attrition or flaking of enamel during treatment or removal.

### Symbols

Symbol	Description
	Indicates the product conforms to the requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation
	For Single Use Only, Do Not Reuse
	Supplied in a non-sterile condition
	Manufacturing lot number
	Catalog number
	Ultimate Wireforms' Orthodontic Wire Devices have not been evaluated for compatibility in an MRI environment. The MRI technician, radiological staff or your doctor should always be notified before any MRI procedure is conducted so that

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Symbol	Description
	the proper actions can be taken. If an MRI is needed, contact the radiologist prior to the procedure for instructions regarding appliance removal, if required. Stainless Steel wires are minimally magnetic and may cause concern for dislodgement or image artifacts.
	Indicates nickel within, related to allergen
	Caution is necessary in regards to use
	Date of manufacture
	Legal manufacturer
	Medical Device
	Indicates the authorized representative in the European Community/European Union

### Part Numbers

Product	Product Description Prefix and Code Prefix	Variants	Material	Composition
beta titanium archwire	CNARC (061)	Wire size, archform, and loop type and loop position	Titanium	79% Titanium (Ti), 11% Molybdenum (Mo), 6% Zirconium (Zr), and 4% Tin (Sn)
beta titanium straight wire	CNSTR (062)	Wire size, and shape	Titanium	79% Titanium (Ti), 11% Molybdenum (Mo), 6% Zirconium (Zr), and 4% Tin (Sn)
beta titanium intrusion archwire	CNCTA (067)	Wire size, archform, and bend placement	Titanium	79% Titanium (Ti), 11% Molybdenum (Mo), 6% Zirconium (Zr), and 4% Tin (Sn)
niti archwire	NTARC (011)	Wire size, shape, archform, and force	Nickel Titanium	55% Nickel (Ni), and 45% Titanium (Ti)

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<b>Product</b>	<b>Product Description Prefix and Code Prefix</b>	<b>Variants</b>	<b>Material</b>	<b>Composition</b>
niti straight wire	NTSTR (012)	Wire size, force, and shape	Nickel Titanium	55% Nickel (Ni), and 45% Titanium (Ti)
niti spool wire	NTSPL (013)	Wire size	Nickel Titanium	55% Nickel (Ni), and 45% Titanium (Ti)
niti torqued archwire	NTTOR (014)	Wire size,	Nickel Titanium	55% Nickel (Ni), and 45% Titanium (Ti)
niti utility archwire	NTUTL (015)	Wire size, archform, bend placement, and tube segments	Nickel Titanium  <b>and</b> Stainless Steel 316L (tubes)  <b>and</b> Stainless Steel 304 ("Z" Legs)	55% Nickel (Ni), and 45% Titanium (Ti)  <b>and</b> 65.75% Iron (Fe), 17% Chromium (Cr), 12% Nickel (Ni), 2.5% Molybdenum (Mo), 2% Manganese (Mn), and 0.75% Silicon (Si)  <b>and</b> Conforms to ASTM A313 (chemistry only)
niti intrusion archwire	NTCTA (017)	Wire size, archform, and bend placement	Nickel Titanium	55% Nickel (Ni), and 45% Titanium (Ti)
copper niti archwire	CUARC (091)	Wire size, shape, archform, and force	Copper Nickel Titanium	49% Nickel (Ni), 44.5% Titanium (Ti), and 6% Copper (Cu)
copper niti straight wire	CUSTR (092)	Wire size, force, and shape	Copper Nickel Titanium	49% Nickel (Ni), 44.5% Titanium (Ti), and 6% Copper (Cu)
stainless steel archwire	SSARC (021)	Wire size, shape, archform, and finish	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel straight wire	SSSTR (022)	Wire size, and shape	.022 diameter and above is Stainless Steel 302	Conforms to ASTM A313 (chemistry only)
stainless steel straight wire	SSSTR (022)	Wire size, and shape	.021 diameter and below is Stainless Steel 304  Square/Rectangle Wire Sizes is Stainless Steel 304	Conforms to ASTM A313 (chemistry only)  Conforms to ASTM A313 (chemistry only)

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<b>Product</b>	<b>Product Description Prefix and Code Prefix</b>	<b>Variants</b>	<b>Material</b>	<b>Composition</b>
stainless steel utility archwire	SSUTL (025)	Wire size, archform, bend placement, and tube segments	Stainless Steel 304 (Arch Form) <b>and</b> Stainless Steel 304 ("Z" Legs) <b>and</b> Stainless Steel 316L (tubes)	Conforms to ASTM A313 (chemistry only)  <b>and</b> Conforms to ASTM A313 (chemistry only)  <b>and</b> 65.75% Iron (Fe), 17% Chromium (Cr), 12% Nickel (Ni), 2.5% Molybdenum (Mo), 2% Manganese (Mn), and 0.75% Silicon (Si)
stainless steel 3-strand archwire	S3ARC (031)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 3-strand straight wire	S3STR (032)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 3-strand spool wire	S3SPL (033)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel coax archwire	SCARC (041)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel coax straight wire	SCSTR (042)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel coax spool wire	SCSPL (043)	Wire size	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 8-braid archwire	S8ARC (051)	Wire size, archform	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 8-braid straight wire	S8STR (052)	Wire size, and shape	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 2 key-loop archwire	S2KLP (123)	Wire size, archform, and loop position	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)
stainless steel 4 key-loop archwire	S4KLP (124)	Wire size, archform, and loop position	Stainless Steel 304	Conforms to ASTM A313 (chemistry only)

**Clinical Benefits**

Orthodontic treatment improves oral and dental health via the correction of dental malocclusions and provides aesthetic improvements.



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Fixed orthodontic appliances are considered the main and most effective types of medical devices to correct orthodontic malocclusions. These appliances are composed of several components that are combined to produce biomechanical forces to move teeth. Treatment using fixed orthodontic appliances may be performed at different stages in patients' lives, such as childhood, adolescence or throughout adulthood.

In the hands of dental professionals, orthodontic appliances are easy to use, remove, and adjust. Fixed orthodontic appliances safely (preventing unwanted side effects) and efficiently move teeth requiring minimal patient compliance, cause minimal discomfort, and limit negative impact on eating or speaking. Routine visits to the orthodontist promote good oral hygiene and reduced occurrence of dental caries (tooth decay).

### Performance Characteristics

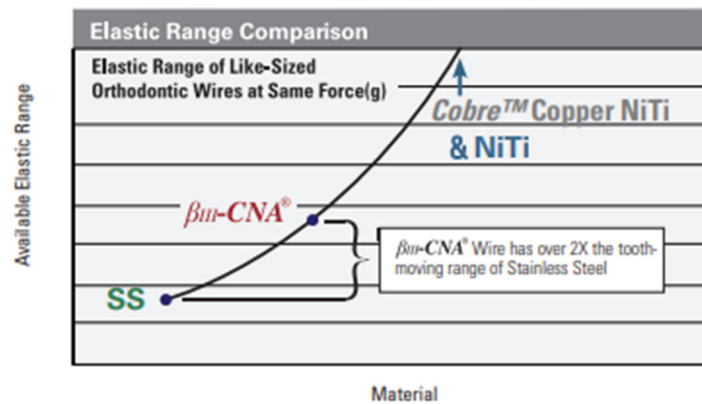
Choosing the proper wire takes knowledge, training, and experience; a range of alloys provides for efficient tooth movement in the hands of orthodontic professionals. Wire material selection, and size provides a range of force magnitudes, and elastic ranges. Reduced force magnitudes yield greater patient comfort, and high elasticity allows for easier ligation and resistance to permanent set. A wide range of materials, sizes, and shapes provides orthodontist with the necessary tools to customize treatment to suit individual patient needs, optimizing functional and aesthetic outcomes.

- Nickel Titanium and Copper Nickel Titanium wire
  - Light to moderate, consistent forces.
  - Responsive to chilling.
  - High flexibility, allowing for easier ligation.
  - Resilient, resistant to permanent set.
  - Gentle forces, more comfortable for the patient.
- Stainless Steel 302 Multi-strand wire
  - Light to moderate force.
  - Limited flexibility.
  - More resilient than solid stainless steel.
- Stainless Steel 304V Solid wire
  - Higher force.
  - Weldable.
  - Easy to bend.
  - Smooth surface, and high stiffness make it a suitable finishing wire.
- Beta Titanium wire
  - Moderate force.
  - Stiffness between nickel titanium and stainless steel, ideal for mid- and late stages of treatment.

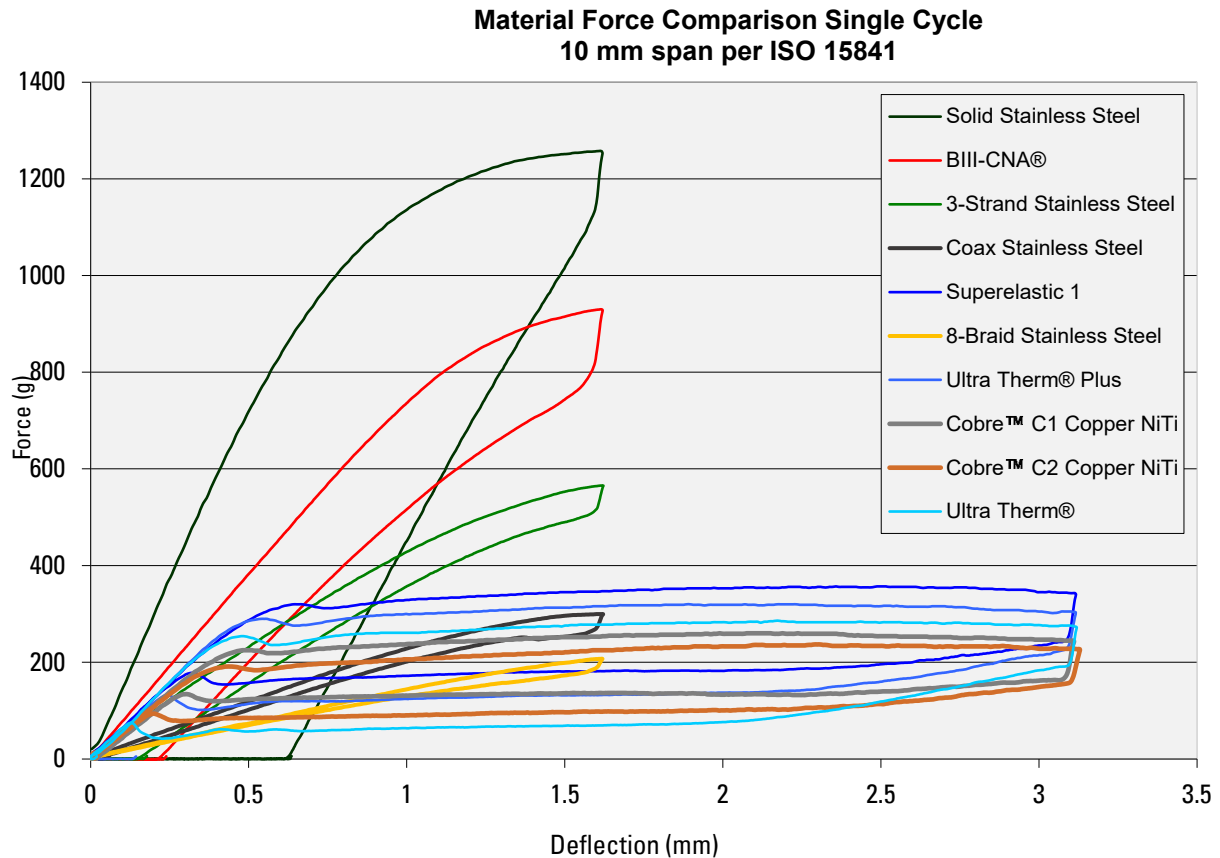
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- High springback.
- Weldable.
- Easy to bend, forming loops, steps, and lever arms.
- Greater activation range than stainless steel.
- Nickel free alloy.

The useful range equates to the length of time the wire is active in tooth-moving. The elastic range is measured with test methods used in determining the stiffness values required for ISO 15841. The stiffer the material, the shorter its elastic range will be at any load level.



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**Instructions for Use**

The use of orthodontic archwires is restricted to dental professionals with qualification in orthodontics. Use by persons outside this context may result in irreversible damage to the patient. The choice of material to be used is made by the qualified professional, based on their knowledge acquired during their training in conjunction with the diagnosis and treatment plan for each patient. Maintenance of the archwires is conducted by the orthodontist during regular inspections when the patient attends repeat regularly scheduled appointments. At these routine visits, the orthodontist checks if the movement of teeth continues to be appropriate. The orthodontist can adjust the archwire/wire and other orthodontic products.

1. Select the archwire to be used for the particular arch.
2. Place the archwire into the bracket slot. Reference archwire midline markings where applicable.
3. Tie the wire with elastomeric or ligature tie (not applicable for self-ligating brackets)
4. Cut off the excess wire at the distal of the furthest most attachment or turn the end of the wire 90 degrees to the lingual (heat activation as necessary), to prevent injuries in soft tissue of the patient.

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5. Patient should be monitored regularly when undergoing orthodontic treatment. Particular care should be taken to monitor for wire distortion.

Any serious incident experienced with the use of the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Maintenance and Storage Instructions**

Store archwire in product packaging until use to avoid wire damage or loss of product identification and trace information.

**Sterilization/Cleanliness**

Orthodontic wires are suitable for use as supplied in a clean non-sterile state. The device does not require sterilization.

**Disposal**

The professional should use good clinical practices for the disposal of medical products in accordance with current state, federal, and National regulations. Possible microbial hazards and infections can be transmitted by the devices contaminated with saliva and possible risk of cuts and pricks from the device when disposed of.

The use of approved sharps disposal containers is recommended.

**Patient Instructions**

Regular visits are required as per the orthodontist prescribed intervals. Missed appointments may lead to longer treatment times.

True orthodontic emergencies are rare. Braces can cause general soreness in the mouth, and teeth may be tender to biting pressures for a few days following adjustment appointments. Eating a soft diet and use of patient wax is recommended to alleviate minor irritations. As a rule, patients should call their orthodontist if pain is severe.

**Change Log**

Revision	Date	Change Summary
A	8/29/2022	Initial release.
B	12/6/2022	Updated the sterilization not to exceed temperature.
C	3/28/2023	Updated the composition table.
D	6/7/2023	Updated: <ul style="list-style-type: none"> <li>• Device description</li> <li>• Warnings and precautions to be taken in the event of malfunction</li> <li>• Which materials contain nickel</li> <li>• Authorized Representative</li> <li>• Sterilization</li> </ul>
E	6/23/2023	Updated Residual Risks & Unintended Side-Effects
F	8/23/2023	Remove sterilization data.

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G	9/23/23	Updated MRI Data Ultimate Wireforms Orthodontic Wire Devices have not been evaluated for compatibility in an MRI environment. The MRI technician, radiological staff or your doctor should always be notified before any MRI procedure is conducted so that the proper actions can be taken.
H	2/27/2024	Presented general warnings and cautions in table format. Added a symbols table.
J	4/18/2024	Elaborated on MRI requirements in order to meet MDR requirements.