

OC-PRO-003-WI-008	Instructions for Use	
	Ortho-Care Orthodontic Wires	

Instructions for Use (IFU) for Ortho-Care Orthodontic Wires

All the Ortho-Care Orthodontic wires are for Professional Use Only.

1. Product Description

Orthodontic wires are non-sterile, single-use medical devices designed to work in conjunction with other orthodontic components, including brackets, bands, tubes, springs, auxiliaries, and elastomers, to align, level, torque, and tip the teeth into proper arch form. These wires exert forces that guide maloccluded or crooked teeth into their ideal positions.

The wires are preformed in an arch shape and are secured to brackets on the teeth using ligatures. They are available in various sizes, cross-sectional shapes, and materials, each offering distinct mechanical properties. Orthodontic wires feature a smooth, shiny finish and are laser-marked at the midpoint with either one dot (Lower) or three dots (Upper) to indicate the appropriate arch form.

Available cross-sectional shapes include round, rectangular, and square. Material options include Stainless Steel, Nickel Titanium (NiTi), Thermal Nickel Titanium (CuNiTi), and Beta Titanium (TiMo). Wires are offered in Upper, Lower, and Universal arch forms. Sizing options include:

Sizing Options

Round	Rectangular	Square
.012"	.014" X .025"	.016" X .016"
.013"	.016" X .022"	.020" X .020"
.014"	.016" X .025"	
.016"	.017" X .025"	
.018"	.018" X .025"	
.020"	.019" X .025"	
	.021" X .025"	

Material Options

Material:	Product Codes Starting:
Nickel Titanium	5323-xxx (10 pack) 5324-xxx (10 pack) 5823-xxx (100 pack) 5828-xxx (10 pack)
Copper Nickel Titanium	5626-xxx (10 pack) 5627-xxx (10 pack) 5826-xxx (100 pack) 5929-xxx (10 pack)
Beta Titanium (Titanium Molybdenum)	5325-xxx (10 pack)
Stainless Steel	5111-xxx (10 / 100 pack) 5811-xxx (100 pack) 5888-xxx (10 pack)

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2. Intended Use/Purpose

Orthodontic wires are non-sterile, single-use medical devices designed to work in conjunction with other orthodontic components, including brackets, bands, tubes, springs, auxiliaries, and elastomerics, to align, level, torque, and tip the teeth into proper arch form. These wires exert forces that guide maloccluded or crooked teeth into their ideal positions.

Orthodontic wires are intended to be used by a qualified healthcare professional in dental or orthodontic practice, designed for use in patients of any gender or ethnicity deemed appropriate for orthodontic treatment.

Orthodontic wires are intended for long term use, in the oral cavity as far as the pharynx, and are intended for single use.

3. Indications for Use

Orthodontic wires are used for the levelling and realignment of dental anatomy, in conjunction with a bracket system in treatment of patients based on a professional's assessment.

4. Intended Users

These devices are intended to be used by a qualified healthcare professional in dental or orthodontic practice designed for use in patients of any gender or ethnicity deemed appropriate for orthodontic treatment.

5. Intended Patient Population

The devices are designed for use in patients of any gender or ethnicity deemed appropriate for orthodontic treatment.

6. Instructions for Use

The dental or orthodontic professional makes the determination on the appropriate devices, material cross sections, and material types, for each unique patient treatment to be performed. The dental or orthodontic professional knows which devices to use at each stage of patient treatment.

The wires are single use devices that are provided non-sterile per standard industry practice.

Re-use may result in reduced mechanical performance, surface damage, corrosion and risk of cross-contamination/infection transmission.

7. Period of Use

- Each wire to be used in the mouth for up to 10 weeks. After 10 weeks, replace with new wire or remove as necessary.

8. Storage & Handling

- Supplied non-sterile.
- Inspect before use; if product is bent, crushed, or damaged, do not use.
- Store at relative humidity $\leq 80\%$, no corrosive gases
- Install only by a qualified orthodontic professional, following normal orthodontic procedures.

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9. Disposal

- Dispose of used devices in clinical or sharps waste according to local regulations.
- Do not discard in normal household waste.
- Used devices may carry biological contamination; appropriate disposal prevents infection.

10. Performance Characteristics & Clinical Benefit

The Orthodontic Wires manufactured by Ortho-Care are used long term to level and realign the dental anatomy in patients whose teeth are misaligned.

They are safe to use long term in the mouth as a body orifice invasive device in contact with the tongue, teeth, and mucous membrane of the mouth.

11. Warnings and Precautions

Clinician Related Warnings/Precautions:-

- This device is intended for single use only.
- This device shall only be fitted, adjusted, and removed by a qualified orthodontist or dentist trained in orthodontic procedures. Patient must not attempt self-installation or adjustment.
- Inspect the wire and packaging before use. Do not use if the product or packaging is damaged.
- Orthodontic wires are supplied in round, square and rectangular shapes in a variety of cross sections (see section 14 for sizes and product codes). Check selected wire size fits any bracket/tube/band or other orthodontic device that it is to be used with, prior to fitting to the patient, to avoid damage to the devices and the appliance breaking.
- In the event of device breakage or choking, report immediately to Ortho-Care. Serious incidents should also be reported to the competent authority for the country in which the incident occurred.
- Check for patient allergies. See section 12, regarding contraindications which includes those allergic to nickel or chromium, and section 16 for list of product codes that contain nickel and/or chromium.

Warnings/Precautions patient must be aware of:-

- Prolonged exposure to acidic fluoride or chlorhexidine-based mouthwashes or other acidic preparations may increase surface corrosion, friction, or metal ion release, reducing mechanical integrity. Advise patients to follow professional guidance on mouthwash use during treatment.
- The patient should be advised to maintain appropriate oral hygiene during treatment to minimize the risk of demineralization, gingivitis, or other oral problems.
- The patient should be advised to avoid carbonated/fizzy drinks during treatment to minimise risk of tooth decay or weakening the mechanical integrity of the device.
- Patients may experience discomfort when wearing the archwires, due to the forces being applied to the teeth and also as the metal may rub against the mouth, cheek, lips or tongue. Orthodontic wax can be used to ease discomfort due to rubbing.
- In the event of device malfunction, breakage or choking:-
 - Remove all loose parts of appliance from mouth,
 - Immediately seek medical assistance if airway could be compromised or there is any injury,

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- Report immediately to clinician and to Ortho-Care and in the event of a serious incident also report to competent authority for the country in which the incident occurred.
- Patients should advise the clinician on any allergies, especially to nickel or chromium.

MRI Safety

- Materials used in components of fixed orthodontic appliances can cause unwanted effects and affect the diagnostic quality of MR images by producing artefacts. Patients are advised to inform MRI staff prior to the procedure so that appropriate action can be taken.
- Ortho-Care Stainless Steel wires are considered MRI Unsafe and must be removed prior to an MRI Scan, as the wire contains some ferro-magnetic material. See section 16 for Stainless Steel product codes.
- Ortho-Care Copper-Nickel-Titanium, Nickel-Titanium and Titanium Molybdenum wires are considered MRI Conditional and must be removed prior to scans of the head and neck, due to the artefacts that can be generated during a scan of this area. See section 16 for product codes that are MRI Conditional.

General risks related to Orthodontic Treatment

- General risks of orthodontic treatment not specific to Ortho-Care orthodontic wires are:-
 - Uncontrolled or excessive tipping of teeth during orthodontic treatment, leading to compromised periodontal or aesthetic outcomes,
 - External Apical Root Resorption,
 - Damage to or loss of the bone supporting the teeth,
 - Relapse following active treatment,
 - Balance issues.

12. Contraindications

- Wires may contain Nickel and Chromium, see product packaging for warning symbols. Risk assess all patients with a known sensitivity or allergy to Nickel, Chromium, or other metallic alloys - as exposure may cause allergic or hypersensitivity reactions.
- Wires are not to be used by laypersons.
- The orthodontist should assess each patient for suitability for use, particularly in patients with active oral infections, gingivitis, or periodontitis, or other significant pre-existing condition.

13. Reporting Serious Incidents

Any serious incident that has occurred in relation to use of this product should be reported without undue delay to Ortho-Care and the competent authority for the country in which the incident occurred.

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14. Technical Information

Cross Sections - Round		Product Codes for:	Product Codes for:
Size (Inches)	Size (mm)	NiTi, Thermal, Beta Titanium Wires	Stainless Steel wires
.012"	0.30mm	5323/ 5324/ 5325/ 5823/ 5826 -012 (Upper) 5323/ 5324/ 5325/ 5823/ 5826 -112 (Lower) 5828-012 (Universal)	5111/5811-112 (Upper) 5111/5811-012 (Lower)
.013"	0.33mm	5929-013 (Universal)	
.014"	0.36mm	5323/ 5324/ 5626/ 5627/ 5823/ 5826 -014 (Upper) 5323/ 5324/ 5626/ 5627/ 5823/ 5826 -114 (Lower) 5828-014 (Universal)	5111/5811-114 (Upper) 5111/5811-014 (Lower)
.016"	0.41mm	5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -016 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -116 (Lower) 5828-016 (Universal)	5111/5811-116 (Upper) 5111/5811-016 (Lower)
.018"	0.46mm	5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -018 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -118 (Lower) 5828-018 (Universal)	5111/5811-118 (Upper) 5111/5811-018 (Lower)
.020"	0.51mm	5323/ 5626/ 5823/ 5826 -020 (Upper) 5323/ 5626/ 5823/ 5826 -120 (Lower)	5111/5811-120 (Upper) 5111/5811-020 (Lower)

Cross Sections – Rectangular & Square		Product Codes for:	Product Codes for:
Size (Inches)	Size (mm)	NiTi, Thermal, Beta Titanium Wires	Stainless Steel Wires
.014" X .025"	0.36 x 0.64mm	5323/ 5324-145 (Upper) 5323/ 5324 -245 (Lower) 5828/ 5929-145 (Universal)	5888-145 (Universal)
.016" X .016"	0.41 x 0.41mm	5323/ 5626/ 5823 -166 (Upper) 5323/ 5626/ 5823 -266 (Lower)	5111/5811-616 (upper) 5111/5811-606 (Lower)
.016" X .022"	0.41 x 0.56mm	5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -162 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -262 (Lower)	5111/5811-612 (Upper) 5111/5811-602 (Lower)
.016" X .025"	0.41 x 0.64mm	5323/ 5324 -165 (Upper) 5324 -265 (Lower) 5828-165 (Universal)	5888-165 (Universal)
.017" X .025"	0.43 x 0.64mm	5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826-175 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -275 (Lower)	5111/5811-715 (Upper) 5111/5811-705 (Lower)
.018" x .025"	0.46 x 0.64mm	5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -185 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -285 (Lower) 5828-185 (Universal) 5929-285 (Universal)	5111/5811-815 (Upper) 5111/5811-805 (Lower) 5888-185 (Universal)
.019" x .025"	0.48 x 0.64mm	5323/ 5325/ 5626/ 5627/ 5823/ 5826 -195 (Upper) 5323/ 5324/ 5325/ 5626/ 5627/ 5823/ 5826 -295 (Lower)	5111/5811-915 (Upper) 5111/5811-905 (Lower) 5888-195 (Universal)
.020" x .020"	0.51 x 0.51mm	5323/ 5823 -220 (Upper) 5323/ 5823 -320 (Lower) 5626/ 5826-320 (Upper) 5626/ 5826-220 (Lower)	5111-220 (Lower) 5111-320 (Upper)
.021" x .025"	0.53 x 0.64mm	5323-215 (Upper) 5323-205 (Lower) 5325/ 5626-205 (Upper) 5325/ 5626-215 (Lower)	5111/5811-215 (Upper) 5111/5811-205 (Lower)

Detailed data on specific material properties - such as austenite finishing temperature, elastic characteristics, and chemical composition - are available to users and competent authorities upon request.

Requests may be directed to info@orthocare.co.uk.

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15. Symbols that Apply to All Ortho-Care Orthodontic Wires

Symbol:	Symbol Meaning and Information that accompanies the symbol:	Symbol:	Symbol Meaning and Information that accompanies the symbol:
	Medical Device		Lot/Batch Number See product wallet for lot number.
	Unique Device Identifier See product wallet for UDI number.		Do Not Use if Package is Damaged
	Manufactured Date See product wallet for manufactured date.		Keep Dry
	Instructions for Use		CE Mark with notified body number
	Manufacturer Ortho-Care (UK) Ltd, 1 Riverside Estate, Saltaire, BD17 7DR, West Yorkshire UK. Tel: +44 (0)1274 533233 Email: info@orthocare.co.uk		Packaging is Recyclable
	EU Authorised Representative Directa AB, Directa AB - P.O. Box 723, Finvids väg 8, SE-194 27 Upplands Väsby, SWEDEN		Product Reference See product wallet for product reference code.
	Single Use		

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16. Symbols Applicable Only to the Specified Orthodontic Wires

Symbol:	Symbol Meaning:	Explanation and Orthodontic Wires that Symbol Applies to:
	Warning – Product Contains Nickel	Product codes starting: 5111-xxx 5323-xxx 5324-xxx 5626-xxx 5627-xxx 5811-xxx 5823-xxx 5826-xxx 5828-xxx 5888-xxx 5929-xxx
	Warning – Product Contains Chromium	Product codes starting: 5111-xxx 5323-xxx 5324-xxx 5626-xxx 5627-xxx 5811-xxx 5823-xxx 5826-xxx 5828-xxx 5888-xxx 5929-xxx
	MRI Unsafe	The following are MRI Unsafe, which Includes ALL Stainless Steel variants, with product codes starting: 5111-xxx 5811-xxx 5888-xxx These wires must therefore be removed prior to MRI scanning.
	MRI Conditional	With the exception of stainless steel wires, the orthodontic wires are MRI Conditional, with product codes starting: 5323-xxx 5324-xxx 5325-xxx 5626-xxx 5627-xxx 5823-xxx 5826-xxx 5828-xxx 5929-xxx These wires must be removed prior to carrying out MRI scans in the head and neck region.

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