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September 2007

# Rapid Development of a Figure Eight Braided Loop Assembly for Precision Soft Tissue Fixation

## Executive Summary

A rapid development programme was undertaken to create a figure eight braided loop assembly in response to an emerging surgical technique requiring precise geometry, secure fixation, and highly repeatable assembly performance.

The construct reconfigured two 70 mm braided loops into controlled figure eight configuration with a defined 15 mm internal spacing, reinforced using USP 4/0 co-braid stitching.

Beyond achieving dimensional accuracy, the programme focused on delivering a manufacturable solution within an accelerated development timeline while maintaining assembly consistency, functional reliability, and future production scalability.

Through controlled assembly design and structured process development, a repeatable manufacturing method was established for producing a geometry-critical braided construct using existing component platforms.

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## The Challenge

The introduction of a new surgical technique created the need for a customised fixation assembly that combined proven braided components into a new functional configuration. Although the individual components already existed, integrating them into a figure eight construct required precise control of geometry, spacing, and reinforcement to ensure consistent clinical performance.

Unlike conventional loop assemblies, even minor variations in spacing, symmetry, or stitch tension could influence construct stability and handling characteristics. The challenge therefore extended beyond producing a functional prototype to establishing a repeatable manufacturing process capable of supporting future production.

Key engineering challenges included:

- Maintaining a precise 15 mm internal spacing between loops
- Preserving loop symmetry throughout assembly
- Controlling stitch tension to prevent geometric distortion
- Achieving consistent button positioning and orientation
- Delivering the solution within an accelerated development programme
- Developing scalable and repeatable manufacturing process

## Engineering Objectives

The programme was designed to:

- Develop a repeatable figure eight braided loop assembly
- Maintain controlled and verifiable 15 mm internal spacing
- Ensure stable, symmetrical construct geometry
- Integrate secure reinforcement without increasing construct profile
- Establish a repeatable assembly methodology suitable for production
- Deliver a rapid engineering solution without compromising quality or consistency

## Development Approach

**Figure Eight Assembly Architecture**

Two 70 mm braided loops were integrated into a controlled figure-eight configuration with strict dimensional control.

**Final Construct**

**Braided Loop Elements**

Two 70 mm braided loops

Defined orientation and alignment

Symmetrical load distribution

Fixed 15 mm internal spacing

**Reinforcement Strategy** USP 4/0 co-braid stitching provided secure fixation, dimensional stability, low-profile reinforcement, and consistent mechanical integrity.

Maintaining the 15 mm spacing without stitch-driven distortion required precise optimisation of assembly order and stitch tension.

## Validation & Performance Assessment

Completed assemblies were evaluated against predefined structural and dimensional acceptance criteria to verify both manufacturing consistency and functional performance.

Validation activities included:

- Verification of 15 mm internal loop spacing
- Loop alignment and symmetry inspection
- Stitch integrity assessment
- Button positioning verification
- Functional handling evaluation
- Overall assembly consistency review

The assessment confirmed that the required figure eight geometry could be reproduced consistently while maintaining secure fixation, dimensional accuracy, and reliable hadling characteristics across multiple assemblies.

## Process Control & Repeatability

A controlled assembly process was developed to minimise variation and ensure repeatable manufacturing performance.

Critical process controls included:

- Standardised component preparation and inspection
- Controlled button positioning
- Defined assembly sequencing
- Controlled stitch tension and knot formation
- Final dimensional verification against established acceptance criteria

By standardising these process variables, the programme reduced operator-dependent variability and established a robust manufacturing methodology capable of supporting future production requirements.

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## Engineering Outcome

The project successfully demonstrated the rapid development of a precision figure eight braided loop assembly that satisfied demanding geometric requirements while establishing a repeatable manufacturing process within a compressed development timeframe.

Key engineering outcomes included:

- Successful conversion of standard braided loops into a controlled figure eight fixation construct
- Consistent achievement of the specified 15 mm internal spacing
- Secure reinforcement using USP 4/0 co-braid stitching
- Improved assembly repeatability through controlled manufacturing methods
- A scalable assembly process suitable for future production

Beyond delivering a functional assembly, the programme demonstrated the ability to rapidly translate evolving clinical requirements into manufacturable braided medical device solutions. It also established a robust assembly methodology that can be adapted to future procedure-specific fixation systems requiring precise geometry, secure fixation, and repeatable manufacturing performance.

## Application Relevance

The engineering principles demonstrated during this programme are directly applicable to orthopaedic fixation systems and other procedure-specific medical textile assemblies where controlled geometry, repeatable manufacturing, and consistent mechanical performance are essential.

**Orthopaedic**

Suspensory fixation systems used in ligament reconstruction procedures, including ACL and PCL repair, where precise loop geometry supports reliable cortical fixation and reproducible surgical outcomes.

**Sports Medicine**

Tendon repair and reattachment systems requiring balanced load distribution, secure fixation, and consistent construct geometry.

**Reconstructive Orthopaedics**

Procedure-specific fixation assemblies where controlled button alignment, precise loop spacing, and dimensional repeatability contribute to stable soft tissue fixation.

**Medical Device Development**

Rapid adaptation of existing braided components into new product configurations, enabling OEMs to respond quickly to evolving surgical techniques while maintaining engineering robustness and manufacturing scalability.

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## Key Takeaways

- Existing braided components can rapidly reconfigured into new procedure-specific fixation assemblies.
- Precise control of assembly geometry, stitch tension, and component positioning is critical to consistent device performance.
- Standardised manufacturing methods reduce variability and support scalable production.
- Rapid engineering development can deliver clinically relevant solutions without compromising repeatability or manufacturability.
- The project demonstrated expertise in translating evolving clinical requirements into robust, production-ready braided medical device assemblies.

***"Rapid engineering, precise assembly control, and repeatable manufacturing transformed an existing braided platform into a procedure-specific fixation construct ready for production."***

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2755 Canyon Boulevard, 1st Floor
Boulder, CO 80302