

Suture Passer Lifespan Manual

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INTRODUCTION

Purpose

- The purpose of this document is to assist the user in determining whether a Cayenne Medical, a Zimmer Biomet Company, Suture Passer has worn to the extent that it is no longer suitable for use.
- If an indicator described in this manual is identified, the suture passer should be returned to Zimmer Biomet as a worn instrument.

Scope

- This manual provides information only applicable to the reusable Cayenne Medical (Zimmer Biomet) Suture Passers listed below:
 - Quattro® Suture Passer (CM-9010)
 - Quattro GT Suture Passer (CM-9010GT)
 - Lock-Stitch® Suture Passer (CM-9010LS)
 - Quattro GTS Side Load Suture Passer (CM-9010GTS)
- This manual is NOT APPLICABLE to the Quattro Suture Passer Needle, or any other Cayenne Medical or Zimmer Biomet Instrument (reusable or single use).

Glossary

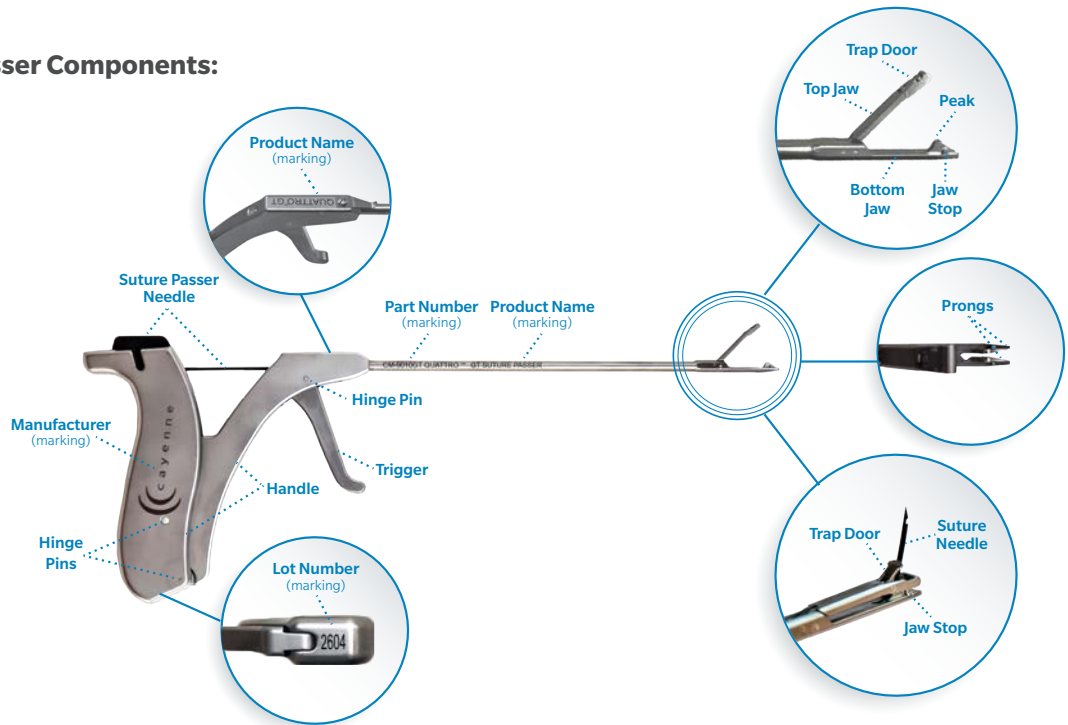
Indicator – a term used to describe damage to a device that can indicate the instrument is no longer suitable for use

Feedback – refers to any specific visual, auditory, or tactile feedback that serves as an indicator of decision/action

Quick Check – an assessment of the instrument's condition to detect the presence of wear

Dry Pass – passing the needle through a clean and dry suture passer, outside of the body and without any bodily fluids providing lubrication.

Suture Passer Components:



Understanding Document Structure

This manual describes several types of wear (i.e. indicators) that a suture passer can undergo, including:

- i. Jaw Closure Misalignment
- ii. Jaw Bending
- iii. Faulty Interaction between Suture Passer and Needle
- iv. Trap Door Malfunction
- v. Protruding Pins
- vi. Worn Laser Marking

The indicators identified above are signs of wear and damage on Cayenne Medical (Zimmer Biomet) Suture Passers, which may indicate that the suture passer should be removed from service. This manual is separated by the indicators identified above. Each indicator section contains the following:

- **Images** representing what each indicator may look like.
- **Symbol legend**
 - ✓ Suitable for Use
 - ✗ Not Suitable for Use
- **Descriptions** of the indicator shown and content specific to the indicator.
- **Potential Effects of Wear** of the Suture Passer specific to the indicator described.
- **Quick Check Methods** to assist the user in assessing the suture passer for the presence of the indicator

Inspection/Function Testing

While loading instruments into their respective instrument cases *after cleaning and prior to sterilization*, reference the manual and follow the instructions below.

- 1 Before each use of the suture passer, reference the manual and follow the instructions below.
- 2 Suture Passers should be inspected for completeness and function, including:
 - a Visual and tactile inspection of the suture passer
 - b Functional testing of the suture passer
 - c Inspecting for all forms of wear outlined in this manual
3. Results of actuation and extent of all forms of wear should be considered in determining whether a suture passer is suitable for use.
4. If the suture passer is determined no longer suitable for use or if the suitability for use is still in question after inspecting the suture passer and referencing the Suture Passer Lifespan Manual, initiate the process to return the suture passer to Zimmer Biomet.

Returning the Suture Passer(s)

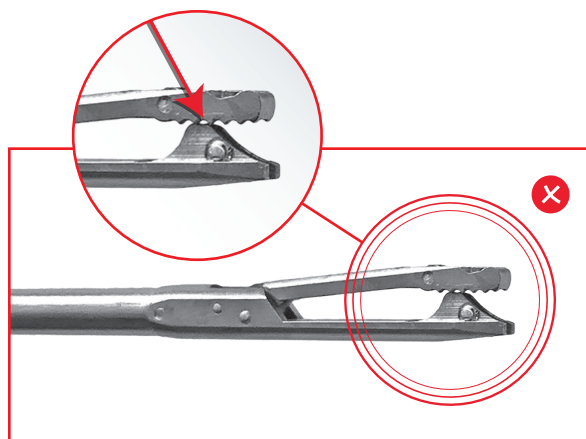
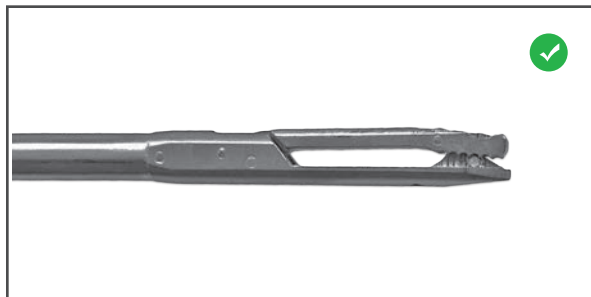
If an allegation is made related to the identity, quality, durability, reliability, safety, effectiveness or performance of a suture passer at any time, outside of this inspection, please complete and submit a Product Experience Report (CF04001) and return the suture passer to Zimmer Biomet for investigation.

If the suture passer to be returned is not part of a complaint, complete and submit a Worn Instrument Return Form (F-01413 D). The Worn Instrument Return Program is not a replacement for the Complaints Submission Process.

Please do not attempt to dispose of the suture passer through any other means.

INDICATORS

Jaw Closure Misalignment



Description

- ✔ **Suitable for Use:** While holding the suture passer sideways and slowly closing the jaw, the top jaw should contact both jaw stops on the bottom jaw (jaw stops are located on the outer part of each peak).

- ✘ **Not Suitable for Use:** The top jaw should never “catch” or come into contact with one of the peaks before contacting the jaw stops on the bottom jaw.

Potential Effects of Wear

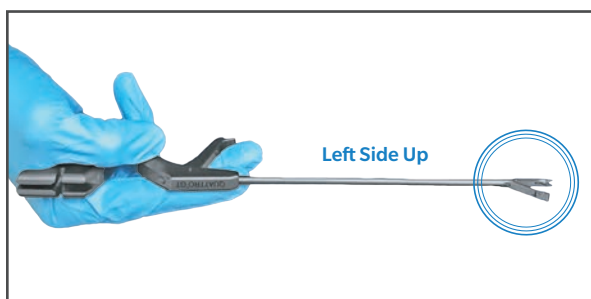
- Suture needle may not pass through the trap door
- Suture passer may misfire (does not pass suture)

Visual and Tactile Quick Checks

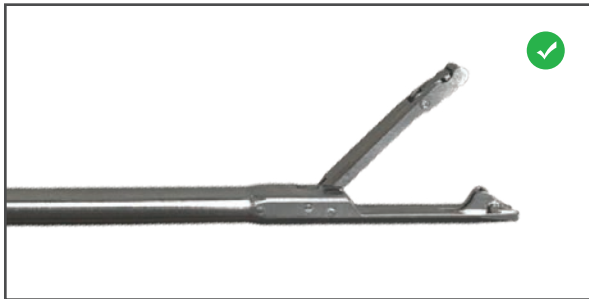
Make sure to check for this indicator while holding the suture passer sideways and inspecting it from both sides (left side up and right side up).

Visual and Tactile Inspection

Hold the suture passer sideways and slowly pull the trigger to close the top jaw. If a “jump” or “catch” is felt as the jaw is closing, or if the top jaw comes into contact with one of the peaks before contacting the jaw stops on the bottom jaw, the suture passer must be returned to Zimmer Biomet.



Jaw Bending



Description

✔ Suitable for Use: The two peaks on the bottom jaw of the suture passer should be perpendicular to one another and aligned with the shaft of the suture passer (up to the distal end of each prong)

✘ Not Suitable for Use: The bottom jaw and/or prong(s) should never appear bent (inwards, outwards, upwards or downwards).

Potential Effects of Wear

- This type of wear can cause misalignment of the needle, which may lead to misfire, and/or premature breakage of the suture needle tip.
- Procedure delay from the device not functioning properly.

Visual Quick Check

Visual Inspection: Inspect the peaks and prongs on the bottom jaw from all sides. If the bottom jaw appears to be bent in any direction (inwards, outwards, upwards or downwards), the suture passer must be returned to Zimmer Biomet.

Faulty Interaction between Suture Passer and Needle

Description



Suitable for Use: When passing an unused Quattro Suture Needle (CM-9011) through the jaw, the needle should pass smoothly.



Not Suitable for Use: There should never be unusual/excessive clicking, grinding, jumping, catching or sticking identified while passing an unused Quattro Suture Needle through the suture passer.

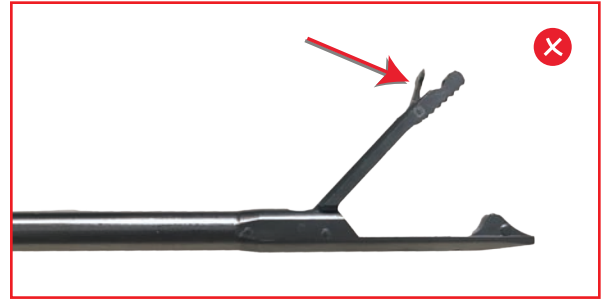
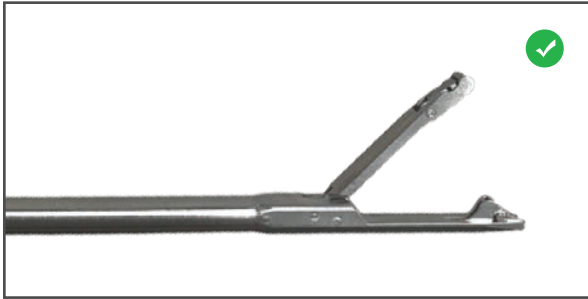
Potential Effects of Wear

- Breakage of the suture needle tip
- Misfire due to the suture needle diverging from its intended trajectory

Tactile Quick Check

- Tactile Inspection: Load a brand new Quattro Suture Needle (CM-9011) into a clean and dry suture passer. Squeeze the handle of the suture passer and 'dry pass' the needle to feel for any roughness, stickiness, catching or unusual/excessive friction. Ensure that the tactile feedback from the needle sliding through the suture passer is smooth when passing the needle (i.e. no grinding, catching, or sticking).
- If unusual/excessive clicks, jumps, grinding, catching or stickiness are identified while passing the suture needle, the suture passer must be returned to Zimmer Biomet.

Trap Door Malfunction (not applicable to CM-9010)



Description

✓ Suitable for Use: The trap door on the top jaw of the suture passer should close completely every time a suture needle is passed up through the top jaw and retracted back into the bottom jaw

✗ Not Suitable for Use: The trap door should never remain open or ajar after a suture needle is passed.

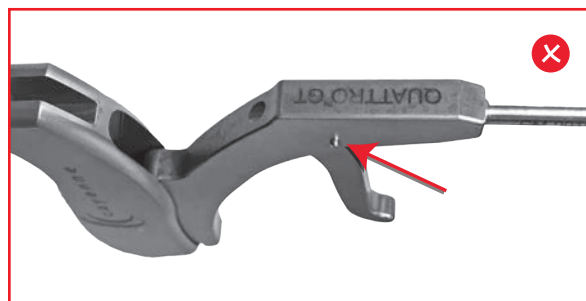
Potential Effects of Wear

- Suture is not captured in the trap door
- Suture slips out of the capture jaw

Visual and Tactile Quick Checks

- Deploy the Suture Passer: Squeeze the trigger and handle of the suture passer to pass the suture needle up through the trap door of the top jaw and then release the trigger and handle, retracting the needle into the bottom jaw.
- Visual Inspection: After passing the suture needle, look at the top jaw of the suture passer to ensure that the trap door has completely closed.
- Tactile Inspection: After passing the suture needle, lightly run a finger along the top jaw of the suture passer to ensure that the trap door is not open or ajar (i.e. sticking up).
- If the trap door is not completely closed upon inspection, clean the suture passer using an alcohol swab or alcohol and brush, and then repeat the Visual and Tactile Quick Checks listed above.
- If the trap door still does not close completely after cleaning the suture passer, the suture passer must be returned to Zimmer Biomet.

Protruding Pins



Description

✔ Suitable for Use: All surfaces of the suture passer should feel smooth and hinge pins should be flush with the surface of the suture passer.

✘ Not Suitable for Use: Sharp edges along the sides or top of the suture passer and/or hinge pins protruding above the surface of the suture passer should never be detected.

Potential Effects of Wear

- Hinge Pin breakage
- Suture passer disassembling
- Trap door/other piece catches on tissue or cannula
- Perforation of gloves and/or sterile barrier

Visual and Tactile Quick Checks

- Visual Inspection: Carefully inspect the suture passer visually to ensure that there are no protruding edges or hinge pins along the sides or top of the device.
- Tactile Inspection: Lightly run a finger along the surface and edges of the suture passer.
- If any sharp or broken edges or protruding hinge pins are identified during inspection on the device, the suture passer must be returned to Zimmer Biomet.

Worn Laser Markings



Description

✓ Suitable for Use: Markings on the suture passer should be clear and easy to read, including the part number, lot number, product name and/or manufacturer.

✗ Not Suitable for Use: Markings on the suture passer should never be worn to the extent that they are illegible to read.

Potential Effects of Wear

- Incorrect identification of the suture passer part number, lot number, product name and/or manufacturer.

Visual and Tactile Quick Checks

- Visual Inspection: Visually inspect the suture passer to ensure that all markings are legible (i.e. part number, lot number, product name and/or manufacturer).
- If any of the markings on the suture passer are illegible to the user, the suture passer must be returned to Zimmer Biomet.

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