



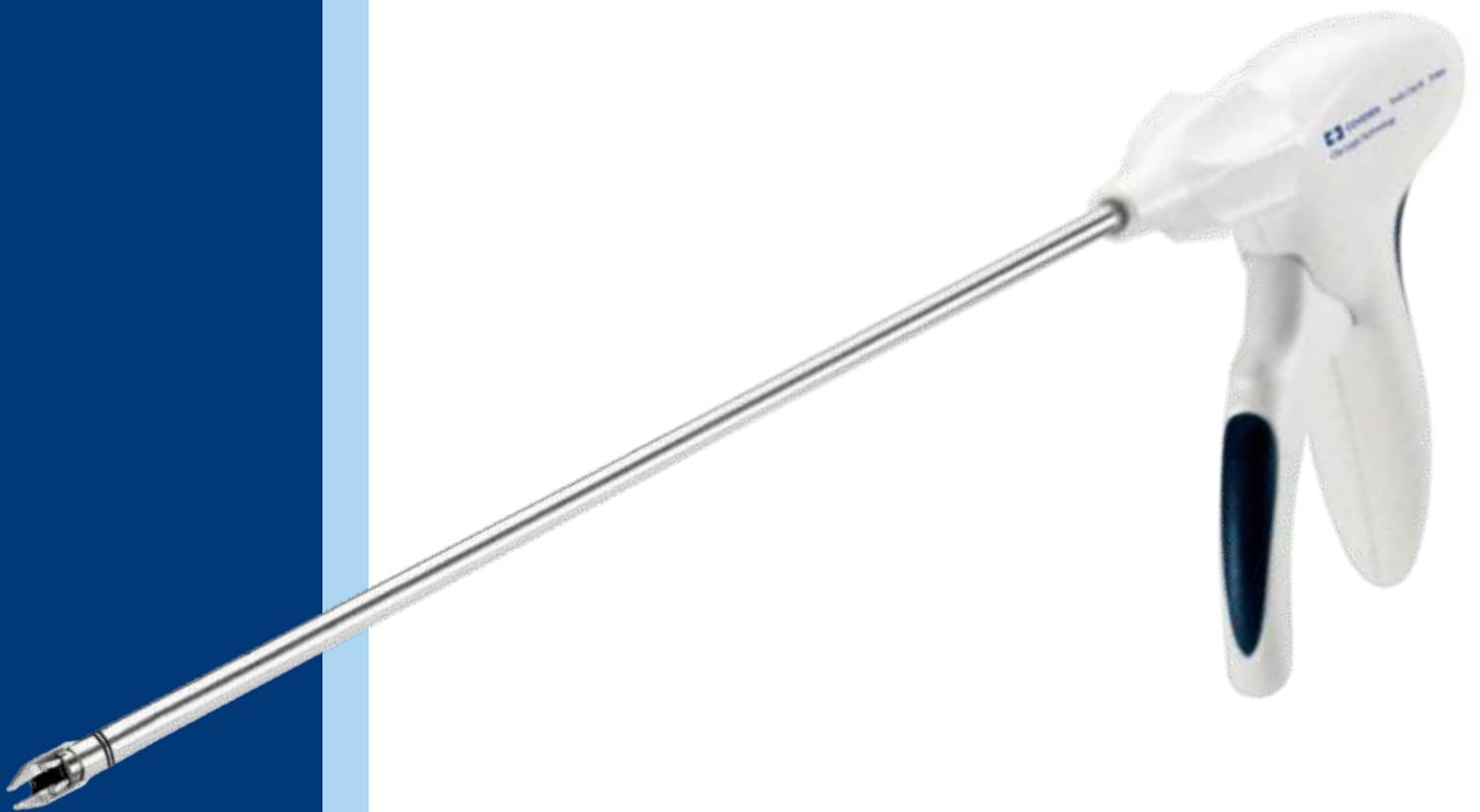
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Redesigned Endo Clip™ III 5 mm Clip Applier

TECHNICAL BROCHURE



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INTRODUCING THE REDESIGNED ENDO CLIP™ III 5 MM

The Endo Clip™ III 5 mm underwent a redesign that yielded improvements in clip security and jaw stability.¹

The critical ligation function has been improved, while retaining the same convenience of the current Endo Clip™ III. This technical brochure details the new U-shaped clip and jaw, from design changes to performance evidence.

FIRST LOOK: WHAT'S NEW

PLEASE REFER TO THE PACKAGE INSERT FOR COMPLETE INSTRUCTIONS, INDICATIONS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS.

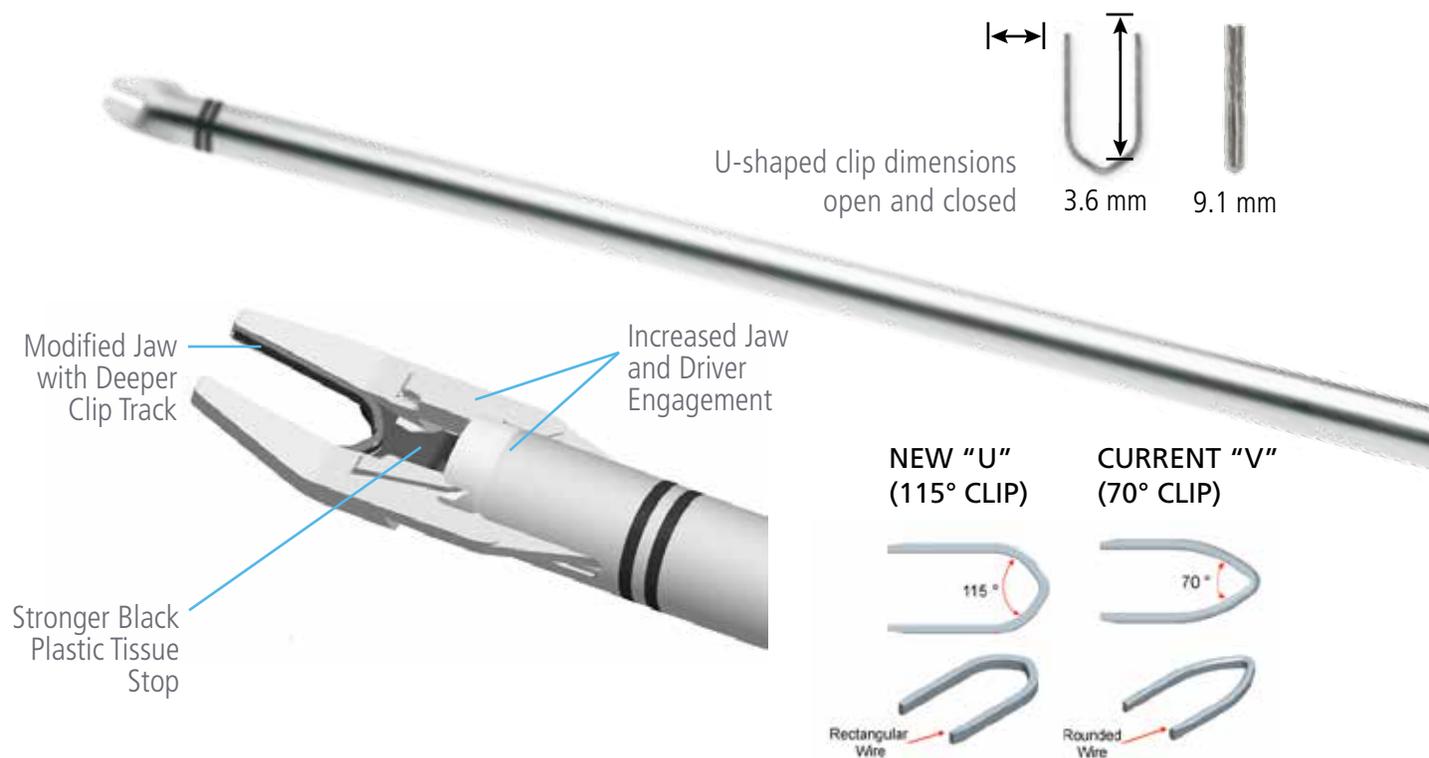


Figure 1: New Design Features

Testing with the new device provided the following evidence:

- **The U-shaped Clip** – Larger back apex and still 9.1 mm when closed
- **A Significantly More Secure Clip** – The new U-shaped clip is 82% stronger than the current V-shaped clip in ex vivo perpendicular pull tests¹
- **Clip Tests Versus the Competition** – The U-clip ex vivo and in vitro tests matched or exceeded the Ligamax™* 5 across the slate of perpendicular pull force tests²
- **A Stronger Jaw** – Jaw and driver are 200% more resistant to disengagement as compared to the V-shaped clip in medial load tests¹

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CHANGES FROM THE CURRENT ENDO CLIP™ III CLIP APPLIER WITH V-SHAPED CLIP

The new U-shaped clip was re-designed from material properties to shape to closure.

CLIP

The new titanium clip has increased strength for a tighter fit on target structures. The new clip has a rectangular profile that also improves stability within the jaws in bottom load tests.¹

DESIGN

The U-shaped clip retains the same size and depth as the V-shaped clip in the current Endo Clip™ III 5 mm, but features a larger back span angle of 115°. The large back span allows target structures all the way into the back of the clip during approximation.

FORMATION

Clip closure is initiated at the distal tips which locks in tissue and forces it to the apex of the clip.

NEW "U" SHAPE



CURRENT "V" SHAPE

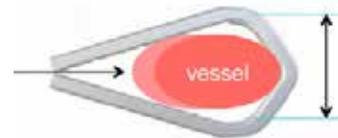


Figure 2: Differences in closure between current V-shaped clip and new U-shaped clip.



Clip counter begins countdown from 16

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A SIGNIFICANTLY MORE SECURE CLIP: U-SHAPED CLIP PULL TESTS

The U-shaped clip is at least 82% stronger than the V-shaped clip in ex vivo perpendicular pull tests (Graph 1).¹

Across all in vitro and ex vivo perpendicular pull tests the new U-shaped clip was significantly stronger than the V-shaped clip (Graph 1).

Perpendicular pull tests measured the force required to laterally pull the clip from the structure. All ex vivo pull tests included 36 trials conducted on porcine carotid artery. All in vitro pull tests included 20 trials each across three Silastic™ tubing sizes (in mm): 1.7, 3.2 and 4.7.

P-Values

In Vitro	Ex Vivo
1.7 = 0.002	= 0
3.2 = 0	
4.7 = 0	

In vitro parallel pull test results show that the U-shaped clip is 46% stronger than the V-shaped clip on 4.7 mm Silastic™ tubing and 28% stronger across all three Silastic™ sizes (Graph 2).¹

Across all tubing sizes the new Endo Clip™ III 5 mm U-shaped clip performed significantly better than the Endo Clip™ III V-shaped clip (Graph 2).

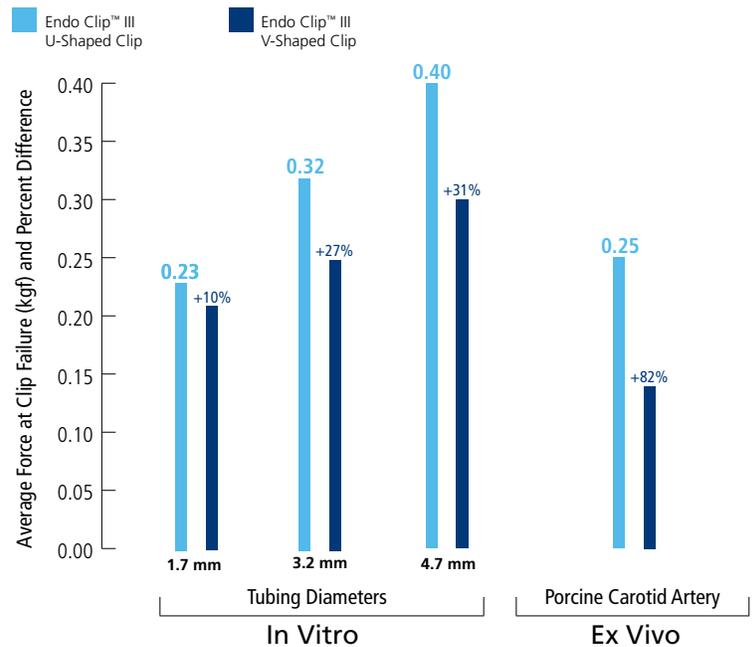
Parallel pull tests measured the force, along the medial axis, required to pull the clip down and off the structure.

All in vitro parallel pull tests included 20 trials each across three Silastic™ tubing sizes (in mm): 1.7, 3.2 and 4.7.

P-Values

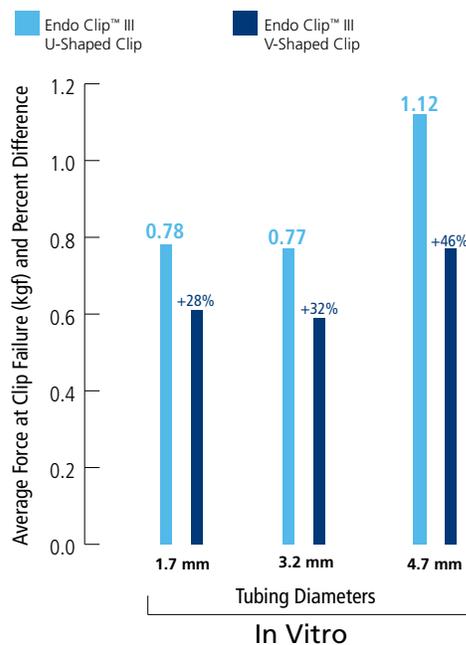
In Vitro
1.7 = 0
3.2 = 0
4.7 = 0

PERPENDICULAR CLIP PULLS



Graph 1: Ex Vivo and In Vitro Perpendicular Pull Results¹

PARALLEL CLIP PULLS



Graph 2: In Vitro Parallel Pull Results¹

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CLIP TESTS VERSUS THE COMPETITION: EX VIVO AND IN VITRO TESTS

The redesigned Endo Clip™ III 5 mm with U-shaped clip matched or exceeded the Ligamax™ 5 across the slate of perpendicular pull force tests (Graph 3).²

U-shaped clip hold forces are equal to the Ligamax™ 5 on porcine carotid artery and higher than the Ligamax™ 5 on all three Silastic™ tubing sizes.

Ex vivo and in vitro perpendicular pull tests are completed with the same number of trials, setup, and materials as noted for previous tests of the same category.

P-Values

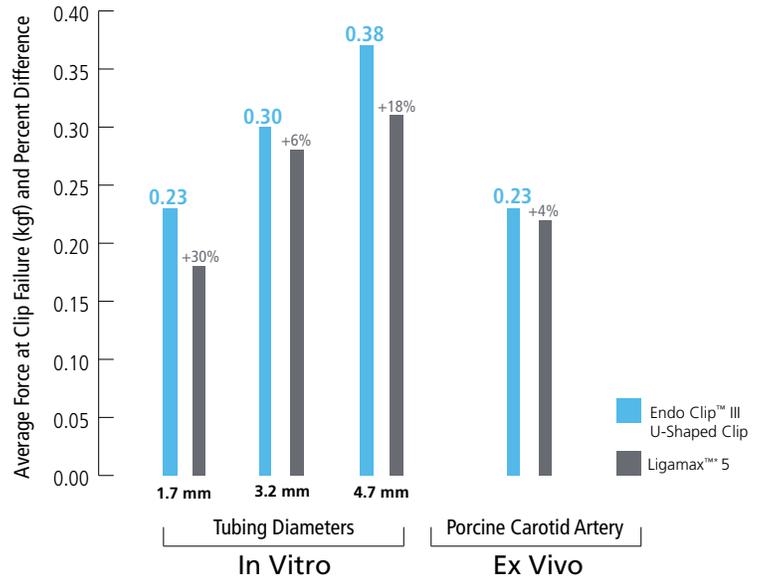
In Vitro	Ex Vivo
1.7 = 0.002	= 0.346
3.2 = 0.001	
4.7 = 0	

The redesigned Endo Clip™ III 5 mm with U-shaped clip performed significantly better than the Ligamax™ 5 in parallel clip pull tests for 3.2 and 4.7 mm Silastic™ tubing sizes (Graph 4).²

P-Values

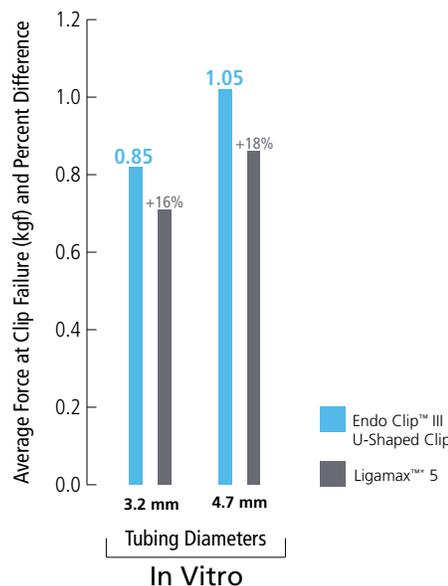
In Vitro
3.2 = 0
4.7 = 0

PERPENDICULAR CLIP PULLS



Graph 3: Ex Vivo and In Vitro Perpendicular Pull Results Against Ligamax™ 5²

PARALLEL CLIP PULLS



Graph 4: In Vitro Parallel Pull Results Against Ligamax™ 5²

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A STRONGER JAW: IN VITRO JAW TESTS

MODIFIED ENDO CLIP™ III 5 MM

CURRENT ENDO CLIP™ III 5 MM

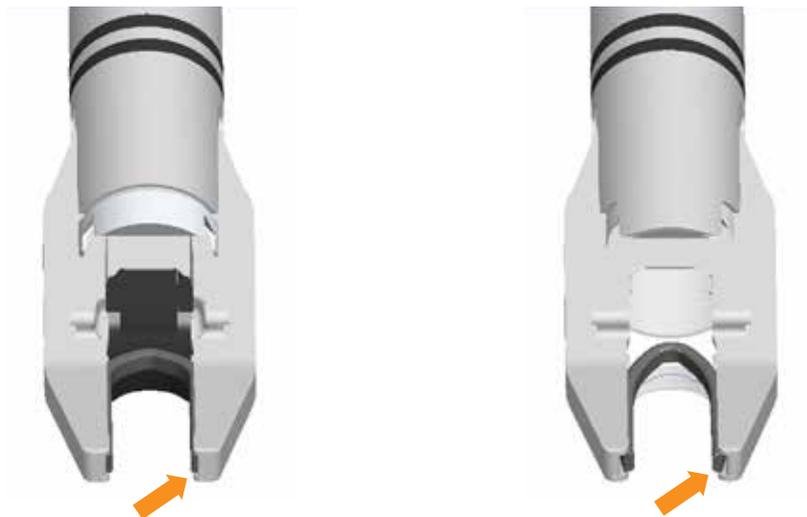


Figure 3: Jaw comparison between current V-shaped clip Endo Clip™ III 5 mm and the redesigned U-shaped clip Endo Clip™ III 5 mm.

The clip logic wedge plate was complemented with a new grouped jaw and driver design. This grouping maintains engagement against medial forces while the wedge plate maintains jaw separation against lateral forces.

Protection against push and pull forces increases stability.

Re-order code	Description
176630	Modified Endo Clip™ III 5mm Clip Applier

The feel and firing sequence are unchanged. Detailed instructions available in the IFU, in-service video or from your Covidien Sales Representative.



NORMAL JAW



DISENGAGED JAW

Figure 4: Normal & Disengaged Jaws.

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A STRONGER JAW: IN VITRO JAW TESTS

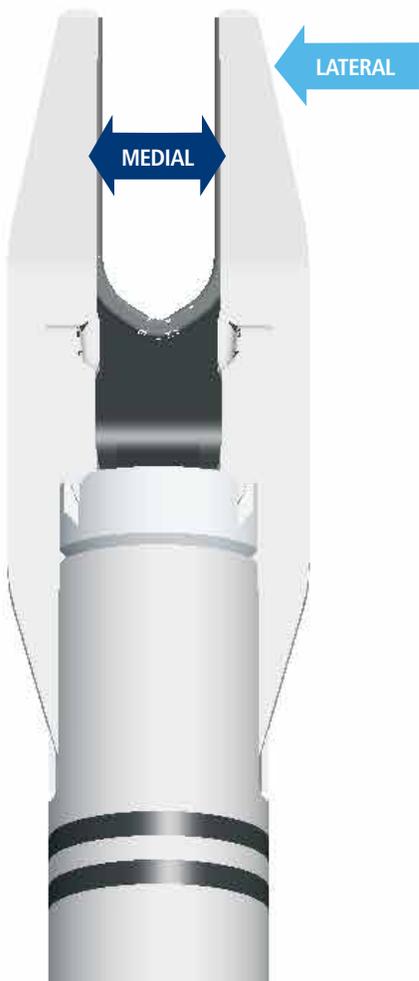
In medial driver disengagement tests, the new jaw is more than 200% resistant to disengagement than the current Endo Clip™ III¹. In medial & bottom force tests, it showed significant improvements over the current Endo Clip™ III (Figure 5).

Medial load tests are conducted with a 22 cm suture loop hitched around one jaw leg and oppositely around the Instron crosshead. The jaw is pulled until disengagement and the force before failure is recorded. Ten trials are run on each jaw leg (See Fig 5). The difference in means for both jaw legs were 229% and 201% greater for the redesigned Endo Clip™ III jaw (P-Values: side A = 0; Side B = 0).¹

Lateral load tests are conducted with the a 200g load applied to the side of the jaws. The devices are fired, noting any loading irregularities or clip malformation. Seven trials per device were performed. (See Fig 5).

Top & Bottom load tests are conducted by approximating the Instron crosshead onto the top and bottom distal regions of the jaws. The crosshead progresses with an incremental force (~100g) followed by the formation of two clips. The force before clip malformation is recorded. Seven trials are run on each side (See Fig 5). The difference in means for the bottom load test were 37% greater for the redesigned Endo Clip™ III jaw (P-Value = 0.008).¹

MEDIAL & LATERAL LOAD TEST



TOP & BOTTOM LOAD TEST



Figure 5: Jaw force diagram with arrows indicating force direction and kg-ft of force sustained before failure. Lateral load test is also shown (inset).



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For more information or to set up a product demonstration, contact your local Covidien Surgical Solutions Representative or call Customer Service at 1-800-722-8772.



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REFERENCES

1. Endo Clip III 5 mm Global Submission Evaluation (Covidien Report # 1424-085-0; report on file, April 24, 2013)
2. Benchmarking: ECIII 5 mm U Clip vs. Ethicon Ligamax 5 (Covidien Report #1424-083-0; report on file, April 24, 2013)

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