

Meril

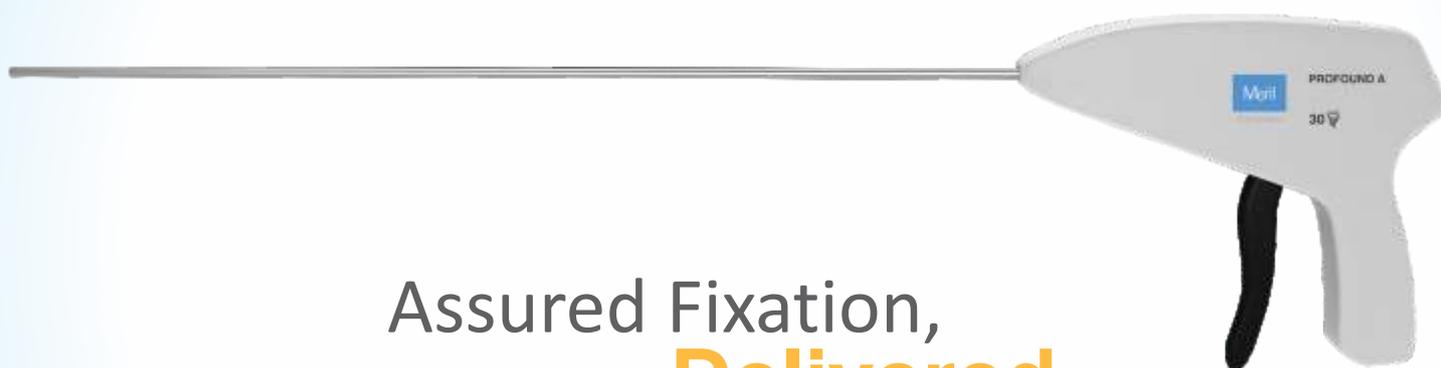
Endo-Surgery



PROFOUND™ A

Poly (lactide-co-glycolide)

Absorbable Mesh Fixation Device for Laparoscopic Hernia Repair



Assured Fixation,
Delivered

Assured Fixation, **Delivered** with 5 benefits for superior surgical outcomes

1. Patient comfort, **Delivered**

Designed with patient comfort in mind

POTENTIAL PAIN REDUCTION

- Mesh fixation can be associated with postoperative pain, possibly due to nerve entrapment.^{1,2}
- **PROFOUND™ A** being an absorbable fixation device offers patients potential pain reduction.³



RELIABLE STRENGTH

PROFOUND™ A retains 85% shearing force of the original at 12 weeks, providing secure fixation during the initial critical healing period

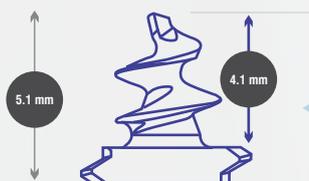


- Absorption of spike essentially complete between 52-54 weeks

2. Trust, **Delivered**

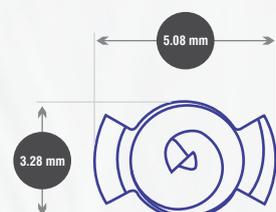
Trusted from its design, to its delivery, to its easy to see colour

Longer spike than the “gold standard” permanent fixation device



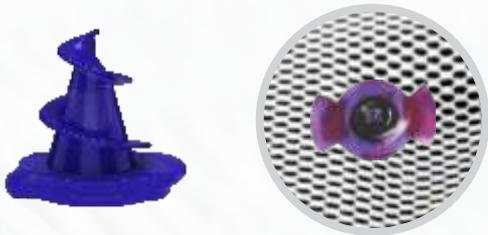
Screw design spikes with sharp exposed tip ensures minimal tissue damage

Wide proximal wings holds larger pore size mesh as well as dual meshes securely, ensuring strong repair



3. Optimal Visibility, **Delivered**

Violet spike



Designed specifically to optimize visibility during surgery

4. Safety, **Delivered**

Needle-less fixation



• Eliminates likelihood of inadvertent needle sticks

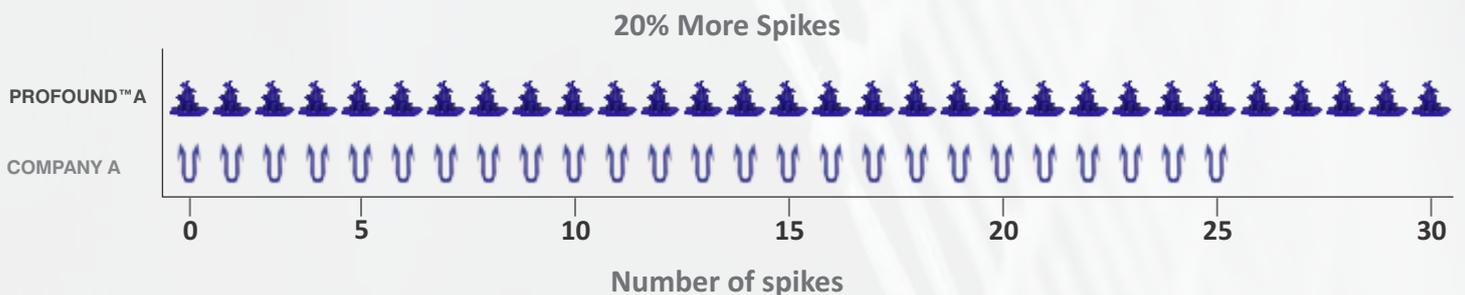
• **20micron extra shaft thickness** – Eliminates the risk of shaft bending especially during fixation of rectangular mesh edges



• Ratchet mechanism for superior tactile feedback

5. More Value, **Delivered**

More Spike. More Choices



PLGA DEGRADATION STUDY - RABBIT ABDOMINAL CAVITY IMPLANTATION STUDY*

Objective of the Study:

To ascertain the strength of spikes over 74 weeks time period.

Observations:

1. One week after surgery, the PLGA spikes were covered by peritoneal membrane.
2. No adhesion were observed between spikes and intestine, no intestinal obstruction were observed.
3. The spikes kept integrated when 26 weeks, and broken when 34 weeks, and solid body disappeared when 44 weeks.
4. After 52 weeks spikes degradation products were found to be disappeared totally.

Conclusion:

1. The absorbable PLGA spikes can be kept integrated in the body until 26 weeks.
2. The spikes strength can be kept at least 12 weeks.

*Data on File

PROFOUND™ A fixation device ordering information

Order Code	Description
MFD15A	PLGA ABSORBABLE 15 SPIKES FOR LAPAROSCOPIC HERNIA REPAIR
MFD30A	PLGA ABSORBABLE 30 SPIKES FOR LAPAROSCOPIC HERNIA REPAIR

REFERENCES

1. Carbonell AM et al. Local injection for the treatment of suture site pain after laparoscopic ventral hernia repair. Am Surg 2003; 69: 688-91; discussion 91-2.
2. Wassenaar E et al. Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques. Surg Endosc 2009
3. Rosen M et al. "Post-Operative Pain After Laparoscopic Inguinal Hernia Repair: Results From a Prospective Randomized Study". 32nd International Congress of the European Hernia Society, October 7, 2010, Istanbul, Turkey

Please refer to the package insert for complete instructions, contraindications, warnings and precautions

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