

Caution “FDA 2011”: A modern pelvic floor mesh with a new form of cranial fixation. An observational study with 6-month follow-up on the A.M.I.® CR-Mesh and i-Stitch

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Abstract: Mesh-augmented pelvic floor surgery, which continues to be the subject of considerable discussion and attention, has not (yet) reached the surgical gold standard. The last 15 years have seen the development of an extensive range of materials and instruments, with the introduction of several revolutionary new methods. However while many of these concepts are a step in the right direction, they are not yet free of risks and complications. A reconstructive technique first demonstrated by Farnsworth was designed to offer full, 3-level support, while allowing individual adjustment of the mesh size and customised cranial fixation. Preliminary results also promised low erosion rates. During April 2008 and March 2010, we carried out an observational study in seven different clinics to evaluate this technique with respect to selected parameters. The study comprised 186 patients with an average age of 65.8 years, who underwent anterior, posterior or total repair with the A.M.I. CR-Mesh. At a follow-up time of 3-6 months, 92.5% of patients were satisfied with the procedure. The most frequent complications were post-operative de novo stress urinary incontinence (SUI) (7.5%) and cystitis (3.7%). Erosion occurred in 3.2% of patients. The authors found the method and materials to be a significant and valuable addition to the range of treatments in mesh-augmented pelvic floor surgery.

Key words: FDA updates; Pelvic floor repair; Prolapse surgery; Urogynecology; Vaginal meshes.

INTRODUCTION

The very topical discussion resulting from FDA-Updates^{1, 2} on the use of mesh for vaginal surgery has prompted consideration of alternative methods and materials, which may provide counter-arguments for many of the claims made by the FDA. The need for sufficient therapeutic procedures to treat pelvic floor defects and prolapse disorders is undisputed and, due to the current demographic development and better education on the subject that is now helping to break existing taboos, the number of patients is increasing. Statistics show that in Germany, more nappies are produced for adults than for children.³

While the field of urogynaecology struggled time and again during the first 100 years with unsatisfactory long-term results, more recent times have been characterised by the quite revolutionary development of new methods born with the introduction of the tension-free suburethral slings (TVT) by Ulmsten and Petros in 1995. The relevant anatomy, and in particular the cranial fixation, can be seen in Figures 1-3. The techniques, materials and instruments that

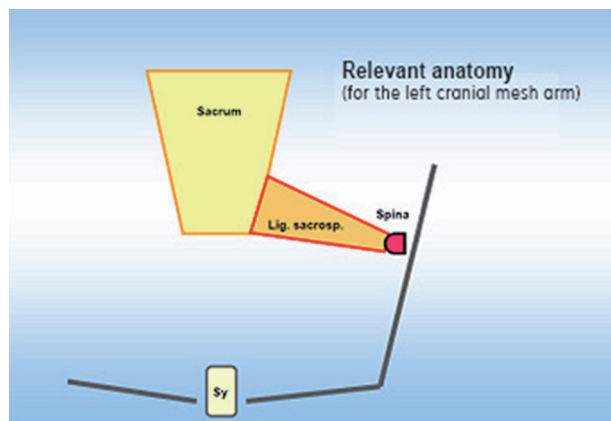


Figure 1. – Relevant anatomy.

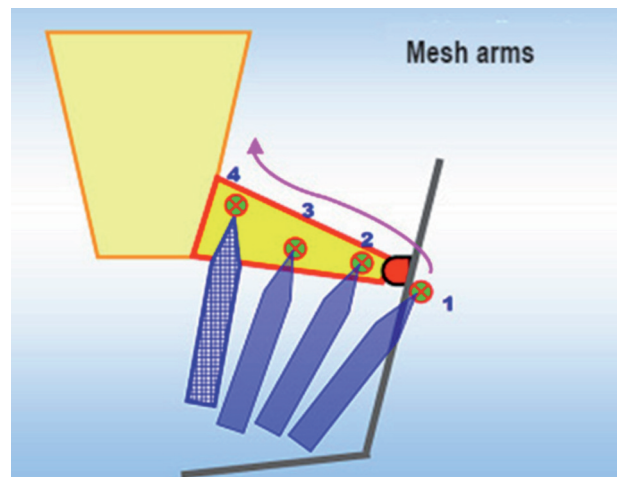


Figure 2. – Cranial passage of mesh arms (fixation point initially at 1, today at 4).

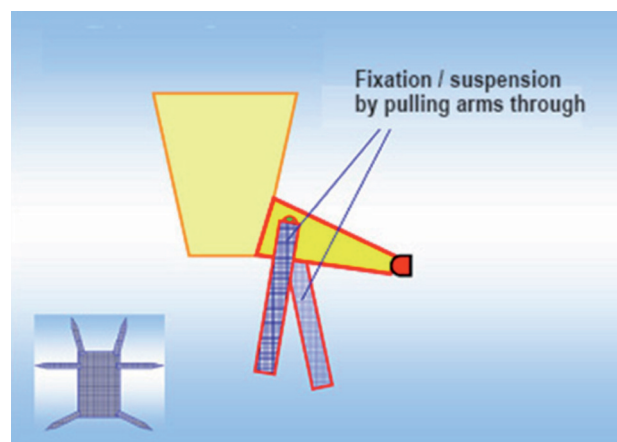


Figure 3. – Passage / fixation of mesh arms.

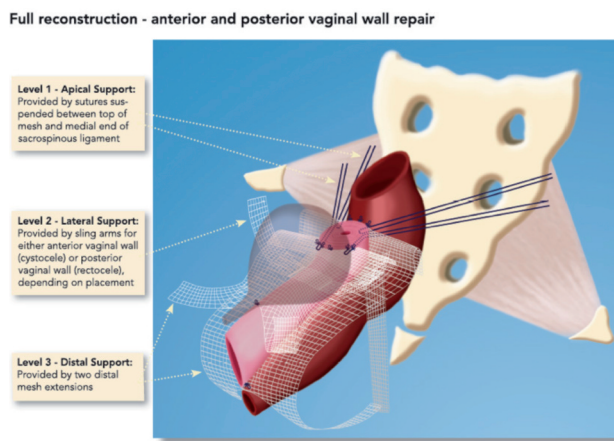


Figure 4. – Technique according to B. Farnsworth.

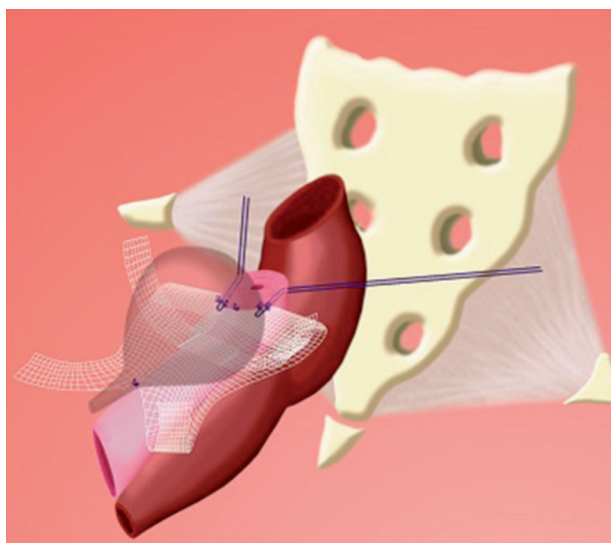


Figure 5. – Anterior repair (cranial suture suspension subsequently replaced by fixation/suspension of mesh arms).

followed all had their own particular emphasis, and some also brought defining and groundbreaking modifications. In particular the transobturatoric approach (Delorme) served as a stimulus for the industry’s activity, and the result was the further advancement of many existing slings and meshes, as well as the introduction of many new ones. Time and again, the significant progress made in terms of effectiveness combined with high success rates achieved by renowned centres provided the impetus for an expansion of the methods, and to some extent also their uncritical use on a broad scale.

We now have an extensive range of innovative procedures, materials and instruments. However, the most recent developments – namely the mini-slings and the first meshes using a purely transvaginal approach – show that while these concepts represent positive progress in many respects, particularly in terms of minimal invasiveness, they are not yet free of risks and complications. In particular the long paths required for placement of the 6-arm meshes primarily used today (for the most part “blind passages” through the pelvis), fixation of the arms – in the case of transobturatoric meshes and slings – to the area of femoral muscle attachment in the upper thigh muscles, as well as a predominant lack of individualised mesh size and fixation, leave many questions unanswered. The “surgical gold standard” for mesh-augmented pelvic floor surgery has thus not yet been found. The road from armless pieces of mesh or patches, on to meshes with 2, 4 or 6 arms with greatly dif-

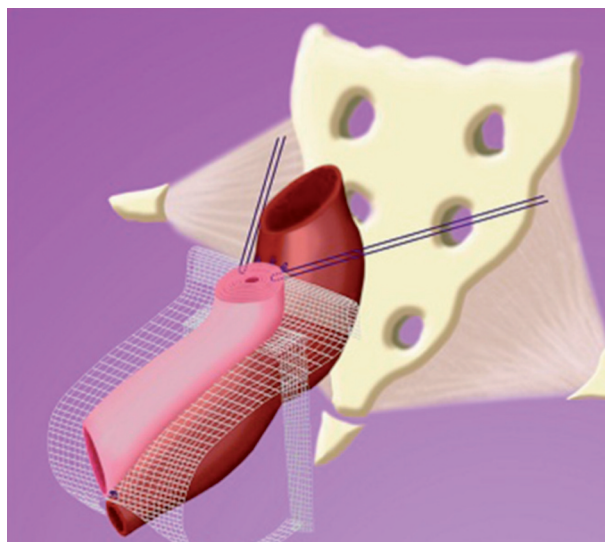


Figure 6. – Posterior repair (cranial suture suspension subsequently replaced by fixation/suspension of mesh arms).

fering fixation techniques, and further on to “unfixed” placement of meshes by means of long-term tamponades, shows the uncertainty of the developers.

Since 2008 a physiological reconstructive technique has been propagated, in particular by B. Farnsworth, who repeatedly emphasised the significance of sufficient, individually-customised cranial fixation and better suspension (Figure 4-6). Preliminary results from other authors have also shown a very low erosion rate occurring with use of this special mesh and surgical technique.⁴ However widespread acceptance of this innovative method was hindered – at least in Europe – by the complexity of numerous individual steps and the inconsistency of still combining a transvaginal with a percutaneous approach.

Our aim was to evaluate this technique with respect to preparation, fixation and customisation.

MATERIALS AND METHODS

During the period from April 2008 to March 2010, the authors evaluated the Farnsworth technique in an observational study comprising seven centres and 186 patients. The average age was 65.8 years and 25.6% of patients had previously undergone pelvic reconstruction surgery (Table 1). The uterus was preserved in 52.2% of patients, and removed in 28% during the same intervention. The remaining 19.8% had previously undergone a hysterectomy. Indic-

TABLE 1. – Patient Population and Case History.

Number of cases	186 patients, 237 meshes (average 31 patients/clinic; range: 4- 7)	
Age of patients	65.8 years (Range: < 50 yrs.: 4.8%; 51-65 yrs.: 42.5%; 66-80 yrs.: 47.9%; > 80 yrs.: 4.8%)	
Case history (%)	After hysterectomy with no further prolapse/defect surgery	17.7
	After hysterectomy with further prolapse/defect surgery	21.3
	Previous prolapse/defect surgery but no hysterectomy	4.3
	No previous surgery	56.7
	Primary reconstruction	74.4
Secondary reconstruction / revision surgery	25.6	

TABLE 2. – Surgery Performed and Operating Times

Surgery performed	n	Operating time (mins)
CR-Mesh + HE	28.0	
CR-Mesh with preservation of uterus	52.2	
CR-Mesh with previous hysterectomy	19.8	
Anterior mesh only	54.3	
+ HE	12.4	82
Preservation of uterus	31.7	63
Previous hysterectomy	10.2	59
Posterior mesh only	12.4	
+ HE	5.9	81
Preservation of uterus	2.7	54
Previous hysterectomy	3.8	49
Anterior and posterior mesh	33.3	
+ HE	9.7	111
Preservation of uterus	16.7	103
Previous hysterectomy	7.0	74

ations for using the A.M.I. CR-Mesh were as follow: anterior and posterior level II defect in combination with level I defect, isolated level I defect, POP-Q III/IV, wish to preserve uterus, long vagina, sexually-active patient.

Operating times ranged from 49-82 minutes for a single mesh with or without hysterectomy, and from 74-111 minutes for a total repair with two meshes, with or without hysterectomy. A total of 237 meshes were placed. 54.3% of patients underwent anterior repair only, 12.4% posterior and 33.3% total repair (Table 2).

Surgery was performed according to the technique described by Farnsworth,⁵ the main steps of which can be summarised in simplified form as follow:

- Preparation of the surgical site in the traditional manner as for anterior, posterior or total repair.
- Placement (for both anterior and posterior meshes) using the i-Stitch instrument of a PP 0 suture on both sides of the sacrospinous ligament, as high and as medial as possible, for level I suspension. This eliminates the need for extensive dissection (Figure 7-10).
- Suspension of the lateral, sleeved mesh arms to the side pelvic wall to provide support at level II.
- Individual customisation of the mesh by cutting the arms with no sleeves down to the correct length. These arms are placed at the bladder neck or around the anal sphincter complex for level III stabilisation.

The focal point of the technique is suspension rather than fixation, and the mesh is designed to establish:

- Stable, individually-customised cranial suspension at level I;
- Firm, but springy muscular suspension and stabilisation at level II;
- A wide, stable connection at level III.

The investigators were asked to evaluate the method and materials in terms of preparation, fixation / suspension using the i-Stitch, individual adjustment of the mesh and physiological repair.

RESULTS

Intra- and post-operative complications, the most common of which were cystitis (7.5%) and de-novo stress urinary incontinence (3.7%), can be seen in Table 3. The cystitis was treated conservatively and subsequently resolved,

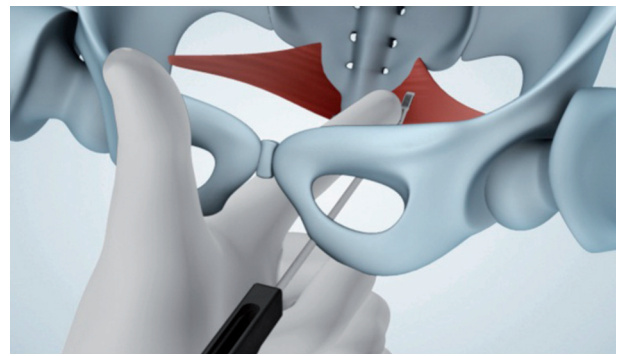


Figure 7. – Suture placement using i-Stitch (1).

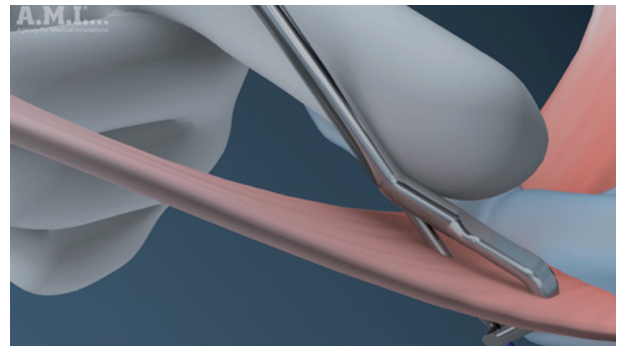


Figure 8. – Suture placement using i-Stitch (2).

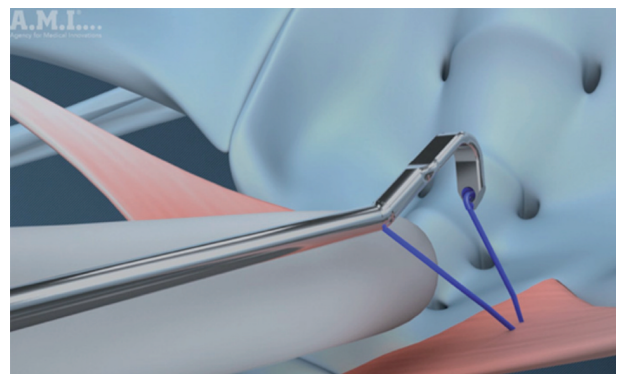


Figure 9. – Suture placement using i-Stitch (3).

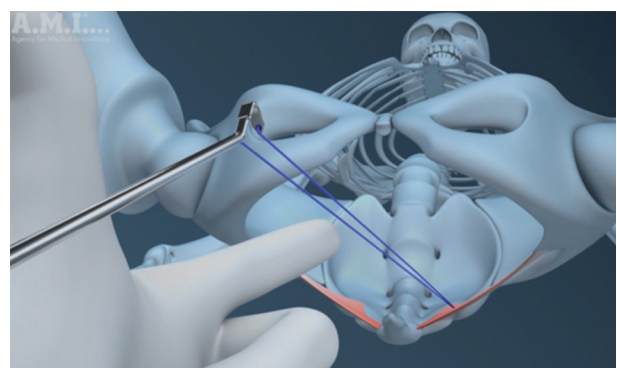


Figure 10. – Suture placement using i-Stitch (4).

while the patients experiencing de-novo SUI received secondary therapy. There was one recurrence of cystocele (0.5%) and one case of de-novo cystocele after implantation of a posterior mesh (Table 3). Multiple cases of short-term urinary retention were successfully treated with conservative therapy. Of the six cases of erosion (3.2%), three were treated with conservative therapy and three patients underwent revision surgery.

TABLE 3. – Complications Intra- and Post-Operative.

Intra-operative bladder lesions	1.6%
Intra-operative intestinal lesions	0.5%
Post-operative cystitis	7.5%
Infected haematoma	1.1%
Post-operative de-novo SUI	3.7%
Recurrence of cystocele	0.5%
De-novo cystocele after posterior mesh	0.5%
Mesh erosions	3.2%

The satisfaction rate, measured according to whether the patient was satisfied with the functional result and would recommend the procedure to others, was 92.5%.

The findings of the investigators in terms of the materials can be summarised as follow:

- The size and shape of the mesh implant allow it to be cut down to suit the individual patient with no difficulty (Figure 11).
- Despite the wide dimensions of the implant, it is easy to handle and the soft texture makes it gentle on the patient. The material is lightweight and isoelastic, while still retaining its shape and stability.
- Even around the edges, the mesh cannot be felt post-operatively and therefore represents no disturbance for sexually-active patients
- The i-Stitch instrument is an innovative solution for suture fixation, allowing easy access to all structures with minimal dissection.
- The authors’ recommendations for modifications to the tunnelling instruments have subsequently been implemented.

The authors find the method to be complex and difficult to perform, with a very flat learning curve. However it offers several notable advantages:

- Optimal, high cranial-medial fixation by means of sutures placed using the i-Stitch, with no excessive preparation and no visualisation of the ligament necessary.
- True, individually-customised apical suspension.
- Optimal adjustment to the patient’s individual vaginal length.
- Preservation of the central vaginal serosa (by median knot fixation of the lateral arms to the mesh body).
- As a result of the specific mesh characteristics and best possible preservation of the physiological vaginal axis, a notably low erosion and de-novo dyspareunia rate.
- Minimal disposable material.

DISCUSSION

Data contained in the Cochrane analyses 2010 and 2011,^{6,7} which along with other publications formed the basis for the FDA warning, require closer scrutiny. There are only two studies relating to quality of life, one study analyses the results obtained with a pre-cut mesh (Perigee), which is applied without the essential apical fixation and therefore implies complications such as mesh shrinking, sintering, creasing, erosions and dyspareunia etc.

Two further studies are based on meshes, which are cut to size instead of pre-cut, but again do not have any form of apical fixation. As qualified by Murphy et al. in,⁸ of the seven randomised studies comparing mesh repair with traditional surgical techniques, six studies were designed to evaluate only anatomical and not subjective outcome, five showed anatomical advantages for mesh surgery while only one study showed no advantage, and only one study contained an analysis of the subjective and objective outcomes. This analysis showed the mesh to achieve better results according to both criteria. In terms of sexuality, only one study showed a significantly worse dyspareunia score in the

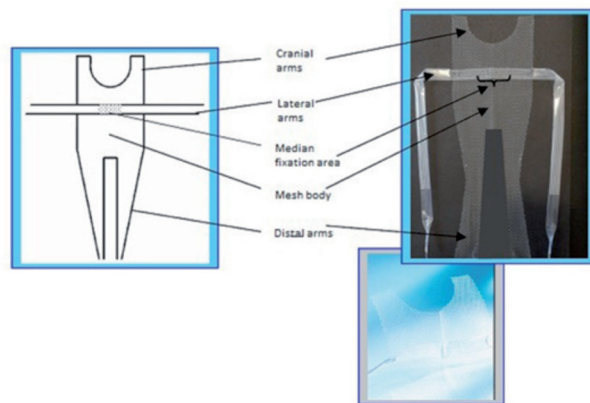


Figure 11. – A.M.I. CR-Mesh (left: basic mesh shape; right: mesh with hexagonal pattern).

non-mesh group, while all the other publications showed no difference between the two. All in all, this collection of literature can therefore be considered as very heterogeneous.

Tunn⁹ also commented objectively:

- There was no differentiation made between the varying qualities of mesh.
- There is no conclusive proof that the complications cited are connected with the mesh implant.
- No mention is made of the fact that similar complications (e.g. dyspareunia) may also arise with prolapse and urinary incontinence surgery which does not involve a foreign body.
- Mesh erosion in the vagina was named as the most frequent complication.
- As there can be no doubt that more than only 7,000 meshes are implanted per year, it would be a remarkably low mesh erosion rate.
- More questions were raised than answered.
- Furthermore, there was no acknowledgement whatsoever of the rapid development made in terms of mesh quality and operating technique.
- Patients must certainly be informed about the lack of long-term results and the availability of other surgical alternatives that do not involve mesh. However to be fair, they should also be informed that particularly in case of a recurrence, there is often no sensible alternative to mesh surgery.

Fuenfgeld qualifies matters further, noting that “many of these meshes were implanted during the learning curve with first generation implants and with a suboptimal technique. The experience described can therefore not be considered a correct representation of today’s reality. At this point in time, the question therefore arises by implication as to what extent the frequently-cited complications might be reduced or prevented by suitable techniques and materials”.¹⁰

There is no doubt that unsatisfactory progress made by individual patients after mesh operations, the accumulation of complications and the discontinuation of studies due to untenable erosion rates require thorough analysis and considered answers. As such, factually grounded, non-tendential warnings, such as that given by Dietl¹¹ should certainly be heeded, however on the other hand we would like to concur with the “snapshot” of the current status as described by Lange: “Colposuspension, suburethral slings and now the meshes have been and continue to be the subject of much controversy. There is no doubt that the field of urogynaecology has made enormous progress and taken a giant leap forwards. Despite making many wrong turns along the way, we now have erosion rates which we previously could only have dreamt of. And with all the criticism of incorrect or incorrectly-applied techniques and the human tendency to see everything new as better, one should

also assess conventional methods just as critically instead of glorifying them".¹²

In this respect, the position taken by the Working Group for Urogynaecology and Plastic Pelvic Floor Reconstruction² may be helpful, according to which: "... a general overly-careful approach to the materials, which in the meantime are very advanced and also quite varied, would not be conducive to scientific progress and would block further developments..."

This also perhaps another good reason to remind ourselves that slings and meshes for incontinence and pelvic floor defects were not simply the random result of a marketing strategy pursued by the industry, instead they were the result of more than 100 years' development, which has been pushed particularly since the 1960's, and of intensive clinical and scientific research. The progress made in the last few years in terms of material and surgical techniques has contributed to the optimisation of therapy and helped objectify the discussion, and is indicative of the primarily responsible manner in which the problems have been handled. Furthermore, the question as to whether – after some 10 years' experience with mesh fixation by means of tapes pulled through the pelvis using tunnellers – the less invasive types of fixation such as anchor systems or other metal fasteners actually have any advantages, is one still under discussion.

We therefore consider the CR-Mesh technique to represent a significant addition to the current range of treatments in mesh-augmented pelvic floor surgery. It incorporates notable advancements in terms of material and method, which appear to address several of the difficulties experienced with mesh implants in the past. In our experience these developments may contribute to improved post-operative outcomes, particularly in terms of erosion and patient satisfaction.

CONCLUSION

Despite considerable discussion during the last few years about the use of mesh implants for pelvic floor repair, mesh-augmented surgery is an important form of treatment and in many cases the only viable option. The CR-Mesh technique according to Farnsworth is a pragmatic and effective method which enjoys a low rate of complications. In particular the stable cranial fixation / suspension created by means of a reusable suture instrument represents a true innovation. Based on a very positive evaluation of the overall concept, and bearing in mind the low erosion rate and high degree of patient satisfaction, the authors consider the method, mesh and instruments to represent a valuable development in the individualised treatment of pelvic floor prolapse.

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