

Palaiseau, July 24th 2020

**URGENT – FIELD SAFETY NOTICE**

**Good practices to implant the medical device LIGAMENTOTAXOR**

Ref : LTX

AREX<sup>®</sup> FSN identifier : **FSCA20200724**

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Subject : Good practices for LTX implantation, following the breakage of a device

For the attention of :

- Responsible of Materiovigilance
- Orthopedic surgeons
- Operating room supervisors
- Users of the medical device LIGAMENTOTAXOR

**Affected device : LIGAMENTOTAXOR**

Following the breakage of a LIGAMENTOTAXOR after its implantation, AREX<sup>®</sup> company has decided to communicate on the good practices for the LIGAMENTOTAXOR implantation, manufactured by the AREX<sup>®</sup> company. This communication concerns all LIGAMENTOTAXOR medical devices placed on the market.

**Description of the incident**

A breakage of the device was identified several days after its implantation, at the beginning of 2019, in a French private hospital.

After investigation, we can confirm that the breakage of the device is the cause of a handling error by the surgeon when placing the medical device. The installation instructions detailed in the "Instruction For Use" manual were not followed by the surgeon.

LIGAMENTOTAXOR is a kit to be assembled by the surgeon. Device breakage occurred on one of the kit components, on the plastic rod at the junction of the cone with the base , as outlined in red in the image below:



During laying of LTX, the step of adjusting the distraction is essential. It is this key step that enables ligamentotaxis. The traction is done clinically with direct control with C Arm machine by pulling on the springs, then it is the screwing that allows precise adjustment. The screwing stops when you reach the plastic cone, without forcing.

The breakage is linked to the fact that the surgeon screwed the springs in forcibly until the base of the plastic rod, which severely damaged the component over the days of installation.

### **Incident risk**

In case of breakage of the base of the cone, the device will no longer hold. This will result in a failed placement which may compromise the surgical procedure.

### **Actions to be implemented by the Customer User**

Before using the device, the user is invited to consult the "Instruction For Use" manual in its entirety, but also to watch the explanatory videos on the assembly of the LTX and on the operation of the Manotte plier. The Manotte plier is essential for the handling of the LTX. The instructions are available in each of the kits sold.

The explanatory videos are available on the website *www.arex.fr*, but also via QR-codes on the outside of all the boxes (without having to open the packaging) of the LTX kits distributed from the first quarter of 2020, as well as in the "Instruction For Use" manual from batch B2563 marketed since May 13<sup>th</sup> 2020.

### **Actions carried out by AREX®**

A communication is sent to all distributors and end customers after every LTX order. This communication focuses on the key point of the assembly of the LTX. It is also joined by the back cover of JHS(E) for the month of May 2020, a reference journal for many surgeons for FESSH (Federation of European Societies for the Surgery of the Hand) and many national societies for the surgery of the hand.

You will find this back cover on the last page of this notification.

### **Additional information and Technical Assistance**

If you need further information or technical assistance regarding this notification, please contact our company at 01-69-41-22-12 or at *info@arex.fr*.

Baptiste LAROCHE  
Responsable Assurance Qualité et Affaires Réglementaires  
AREX®

*Back cover of JHS(E) for the month of May 2020*

## LIGAMENTOTAXOR

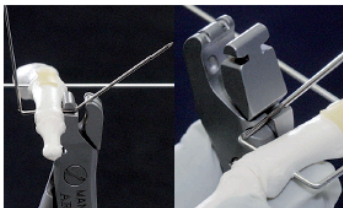
DYNAMIC EXTERNAL FIXATION



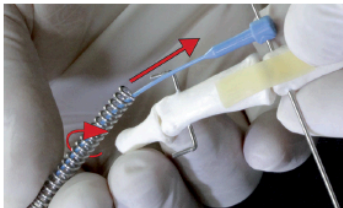
**1. CORRECT POSITIONING WITH DRILL GUIDE**



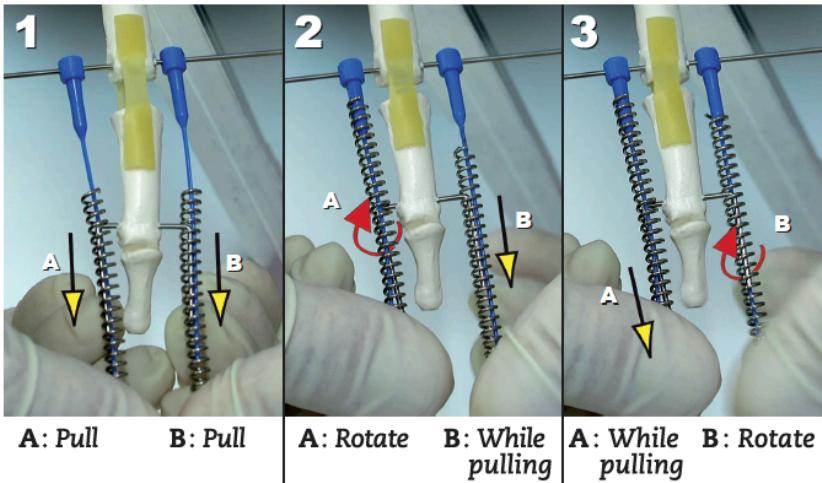
**2. BEND & CUT WITH MANOTTE 1.6TB PLIERS\***



**3. EASY PLACEMENT SPRING**



**4. SPEEDY ADJUSTMENT**



\* The MANOTTE 1.6TB pliers are sold separately.



**EASY ASSEMBLY**



LIGAMENTOTAXOR assembly



[www.alex.fr/QRc.php?c=1](http://www.alex.fr/QRc.php?c=1)

**The LIGAMENTOTAXOR SET includes:**

- 2 LONG PLASTIC WIRES
- 2 SHORT PLASTIC WIRES

So surgeon can choose.  
Lateral view possible with longer plastic wire base.

**AREX®**

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