

## SURGICAL TECHNIQUE



**bioBLOCK™**

Resorbable Subtalar Implant



*"Elegant Solutions for Extremity Challenges"*

## DESCRIPTION

The bioBLOCK implant is a resorbable arthroereisis device constructed of poly-L lactic acid (PLLA). It is designed to provide support and hold the foot in alignment while adjunctive procedures heal.

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# bioBLOCK™

## Resorbable Subtalar Implant



## bioBLOCK SYSTEM OFFERS THESE UNIQUE FEATURES:

- Constructed of poly-L lactic acid (PLLA).
  - Barrel-shaped implant provides optimal medial support.
  - Uniform implant diameter minimizes lateral discomfort.
  - Cannulated, color-coded instrumentation simplifies surgical procedure.
  - Driver allows viewing under fluoroscopy.
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## INDICATIONS

- Internal support to primary surgical interventions in the treatment of flatfoot and posterior tibial tendon dysfunction.
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## CONTRAINDICATIONS

- Vertical calcaneus
  - Rigid flatfoot (unreducible)
  - Rearfoot varus
  - Peroneal spasm
  - Ankle joint valgus
  - Excessive ligamentous laxity
  - Degenerative disease of the subtalar joint
  - Severe obesity
  - Asymptomatic flatfoot condition
  - Patients less than 3 years of age
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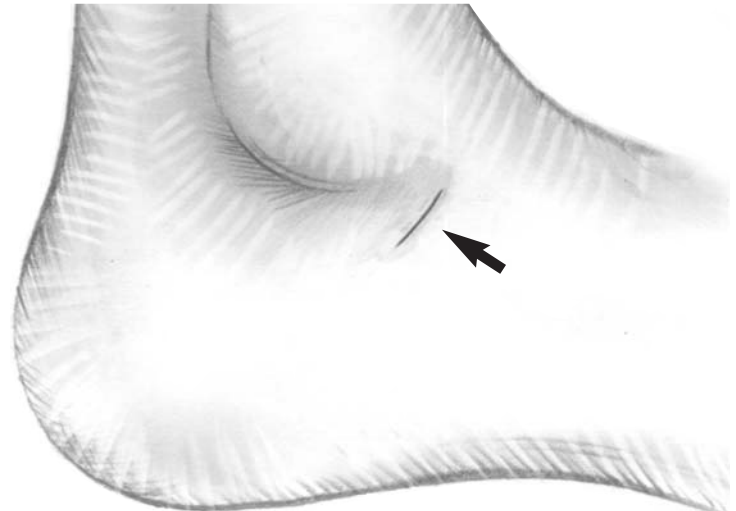
## PRE-OPERATIVE CONSIDERATIONS

In order to ensure the bioBLOCK provides adequate support and correction, KMI recommends that the bioBLOCK implant **not be used in patients weighing more than 250 pounds**. Exceeding this weight guideline may cause the shape of the implant to change, resulting in deformation of the implant shape. The implant may still provide support and correction in this altered state, however it is not recommended.

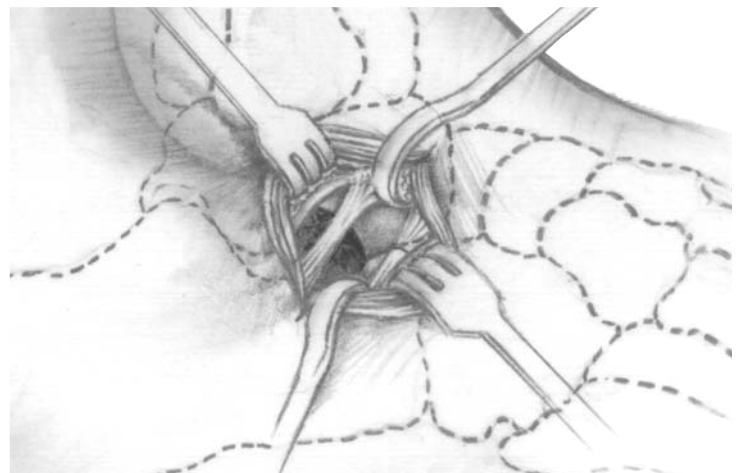
STEP  
1

### INCISION AND DISSECTION

- Make a **1-3cm incision over the sinus tarsi** along the relaxed skin tension lines (**Figure 1**).
- The intermediate dorsal cutaneous nerves should course superior to the incision.
- The sural nerve should course inferior to the incision.
- Incise the deep fascia.
- The anterior lateral edge of the posterior facet of the calcaneus should be palpable with instrumentation upon completing the dissection into the tarsal canal (**Figure 2**).



(FIG. 1)

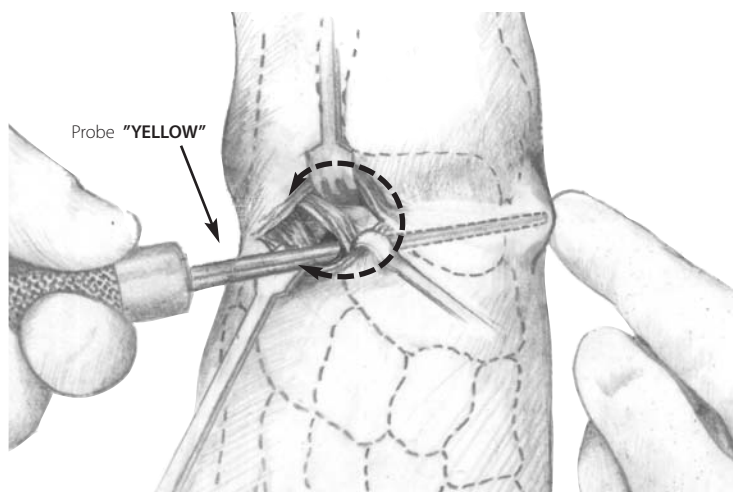


(FIG. 2)

STEP  
2

### PROBE INSERTION

- Insert the yellow Probe instrument **through the sinus tarsi into the sinus canalis** from lateral to medial until tenting is noted on the medial aspect of the foot (**Figure 3**).
- The Probe should be positioned perpendicular to the lateral wall of the calcaneus, **angled slightly posterior and superior**.
- Move the Probe in a clockwise and counter clockwise direction to **slightly dilate** the tarsal canal.
- Remove the Probe.

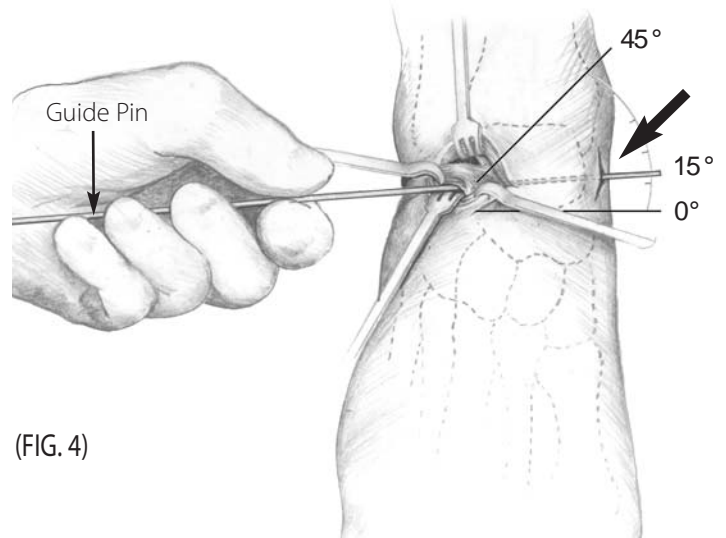


(FIG. 3)

**STEP 3**

## GUIDE PIN INSERTION

- Insert the Guide Pin and make a **small incision medially** to allow the Guide Pin to exit through the medial aspect of the foot (**Figure 4**).
- The distal aspect of the Pin should exit the skin just inferior to the tibialis posterior tendon and anterior and slightly inferior to the medial malleolus.

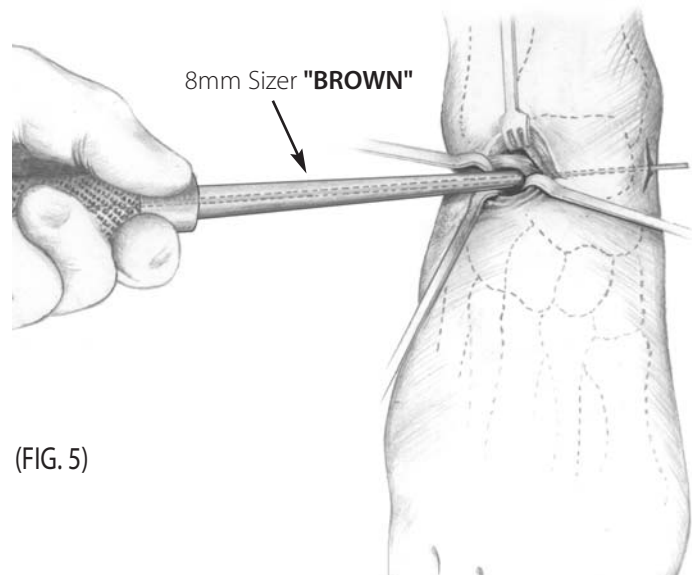


(FIG. 4)

**STEP 4**

## SIZER INSERTION

- Place the cannulated, **8mm Sizer** over the Guide Pin and insert it **through the sinus tarsi into the sinus canalis** from lateral to medial (**Figure 5**).
- Assess the range of motion of the subtalar joint.
- Continue to insert the remaining Sizers (9, 10, 12mm) until proper correction is achieved.
- The appropriate size will allow approximately **2-4 degrees of subtalar joint eversion**.
- An 11mm bioBLOCK Implant is available; however, there is not a corresponding **11mm Sizer**. If the 12mm sizer **over-corrects** the deformity, and the 10mm Sizer provides **too little correction**, the **11mm** implant is recommended.

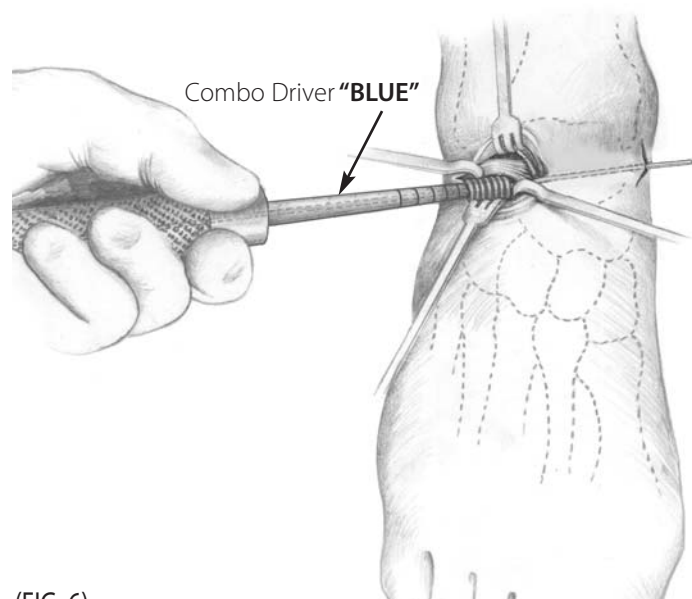


(FIG. 5)

**STEP 5**

## TRIAL IMPLANT INSERTION

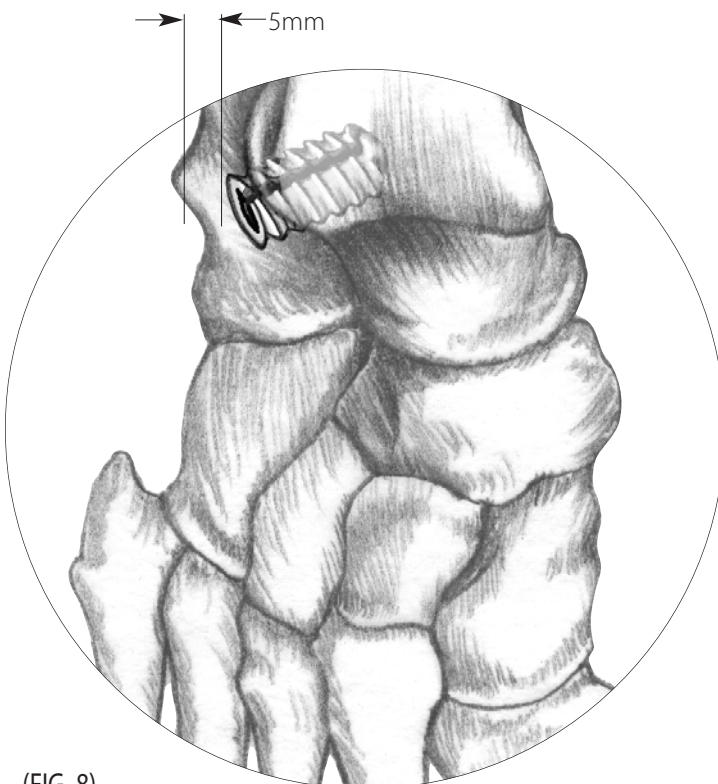
- After the appropriate size is determined, remove the sizer.
- Insert the **corresponding trial implant** using the cannulated **3.5mm hex side** of combo driver (**Figure 6**) (refer to page 7).
- Assess the range of motion of the subtalar joint.
- **Use intra-operative imaging** to evaluate the degree of correction and placement of the trial implant.



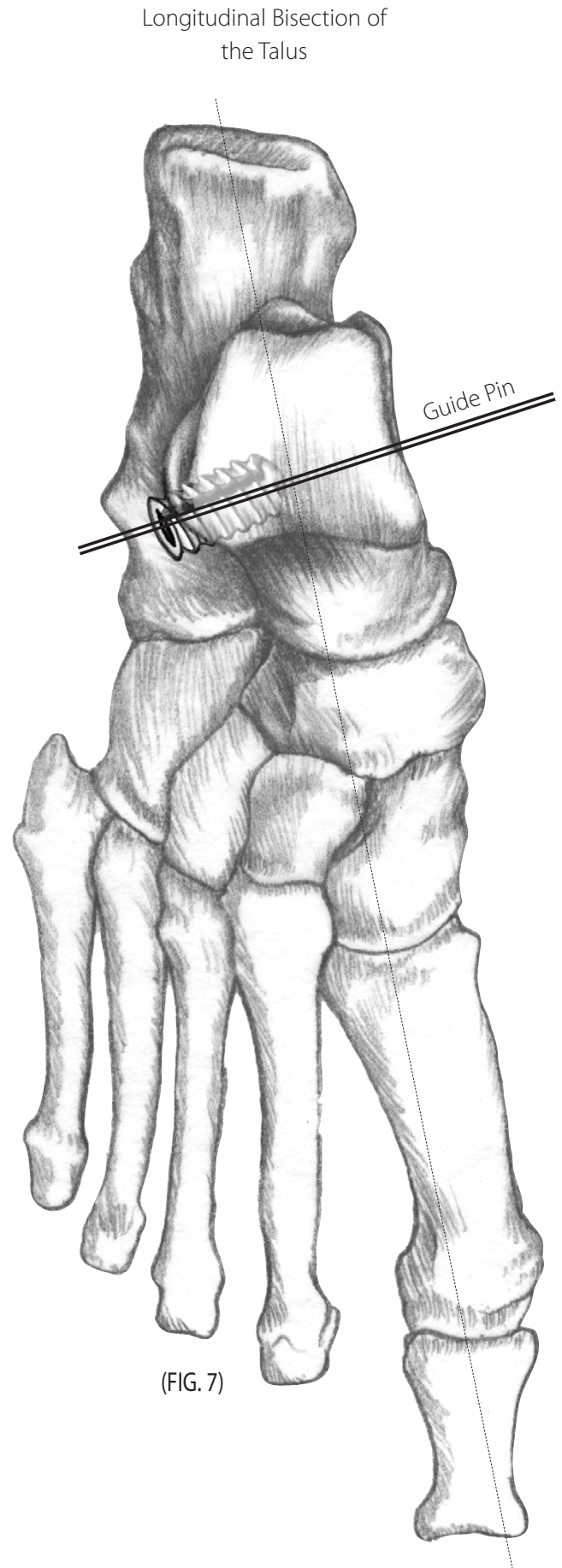
(FIG. 6)

## INTRA-OPERATIVE RADIOGRAPHS

- To determine the correct position on AP view, the leading edge of the Trial Implant should **approach, but not cross, the longitudinal bisection of the talus (Figure 7)**.
- The trailing edge of the Implant should be at least 5mm medial to the lateral wall of the calcaneus (**Figure 8**).
- Examining the lateral view, the Trial Implant should be **angled posterior**, and the Implant should not be sitting on the floor of the calcaneus.



(FIG. 8)

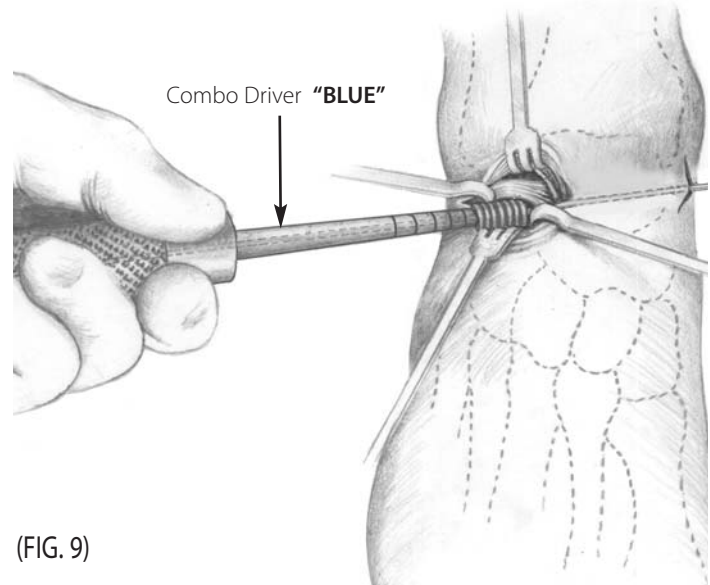


(FIG. 7)

## STEP 7

### IMPLANTATION

- Once the appropriate sized Trial Implant and placement is determined, remove the trial implant.
- The **equivalent size sterile implant is placed** onto the **torx side** of the combo driver over the Guide Pin and threaded in a **clockwise direction** until clinical correction is noted (**Figure 9**).
- Intra-operative imaging is essential to verify proper positioning of the implant (**Refer to Step 8**).
- Once the Implant has been properly positioned, assess the range of motion of the subtalar joint.
- The appropriate size will allow **2-4 degrees of subtalar joint eversion**.

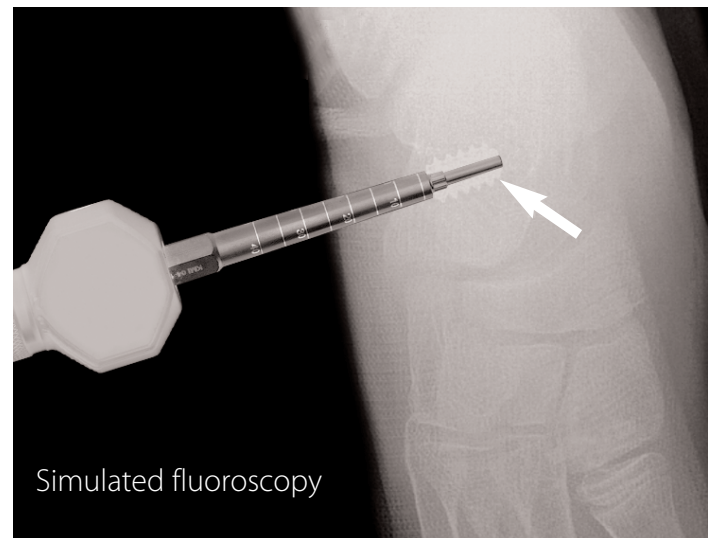


(FIG. 9)

## STEP 8

### INTRA-OPERATIVE IMAGING

- The bioBLOCK Implant is **not visible** under fluoroscopy, but the leading and trailing edges of the Implant may be viewed **using the insertion tool (Figure 10)**.
- The Insertion Tool is left in place during imaging. **The leading edge of the tool indicates the leading edge of the Implant.**
- It is recommended that the Guide Wire be **retracted laterally** into the Placement Driver, so that only the tip of the driver is visible under fluoroscopy.
- The trailing edge of the Driver's torx feature indicates the trailing edge of the Implant.



(FIG. 10)

## STEP 9

### GUIDE PIN REMOVAL AND CLOSURE

- Remove the Guide Pin **medially** when satisfactory positioning of the bioBLOCK Implant is obtained.
- Copiously irrigate the area with saline and reevaluate subtalar joint motion.
- Close the deep tissue, fascia, subcutaneous and skin layers.
- Place the foot in a mildly compressive dressing.

### POST-OP/FOLLOW-UP

- Restrict ambulation for the first 48 hours followed by protective weight-bearing in a removable, below-the-knee, walking cast for two weeks.
- Allow a gradual return to activity over the course of the next month.
- Typically, adjunctive procedures are performed. The appropriate post-operative care should be followed for these procedures.

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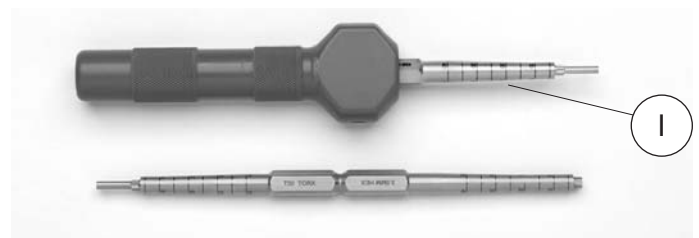
Resorbable Subtalar Implant



## INSTRUMENT TRAY



- A** Probe
- B** Sizers  
6mm, 8mm, 9mm, 10mm, 12mm
- C** Guide Pin Holder
- D** Trial Implants  
6mm, 8mm, 9mm, 10mm, 12mm
- E** Insertion Tool
- F** Insertion Tip Extractor
- G** Insertion Tip
- H** Guide Pin 2mm (.078 in.)
- I** Combo Driver



### bioBLOCK Driver

- The insertion tool used to place the implant is double-sided, with a 3.5mm hex on one end of the driver and a torx on the opposite end of the driver.
- The metal portion of the driver may be removed from the blue handle to switch between the two different interfaces.
- To switch from the hex to the torx interface, pull the metal portion away from the blue handle. To expose the torx interface, flip the metal portion over, and insert the 3.5mm hex interface into the blue handle.

# bioBLOCK™

Resorbable Subtalar Implant

*The Next Step in  
Subtalar Implants*



## FEATURES

- Constructed of poly-L lactic acid (PLLA).
- Provides temporary support while adjunctive procedures heal.
- Ideal for patients with metal sensitivity.
- Provides an alternative treatment option to a metallic device.
- Simple, minimally-invasive surgical procedure.
- Driver allows viewing under fluoroscopy.

PART NO.	DESCRIPTION	SIZE
04-0008	Subtalar Implant	8mm
04-0009	Subtalar Implant	9mm
04-0010	Subtalar Implant	10mm
04-0011	Subtalar Implant	11mm
04-0012	Subtalar Implant	12mm
05-0017	Guide Pin	2mm (.078 in.)
04-1040	Combo Driver	
05-5000	Instrument Set	

## INSTRUMENT SET



04-1040 Combo Driver

## COMPONENT MATERIALS

- Subtalar Implant: poly-L lactic acid (PLLA)



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