



Jazz™ Platform

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MKJAZSFDF18090GB

Surgeon Hopes: Function & Feature

1. Relieve Pain,
2. Mobility: Minimum fusion,
3. Lung capacity: Trunk Height & AP thoracic Distance,
4. Long term results: the non fused spine,
 - Frontal & Sagittal balance,
 - Prevention Junctional Kyphotic evolution,
 - The Junctional lower disk,
 - T1 tilt, Shoulders alignment
5. Keep Options Open.

Hooks:

- No initial stability,
- Unidirectional stability,
- Usually « peak type » load distribution.

Sublaminar wires:

- Easy to use,
- Neurologic complications (?) / dural tears at removal,
- High contact stresses.

Transverse / Spinous process wires:

- High contact stresses,
- Reduction?

Screws:

- Learning curve,
- Navigation, pedi-guards, fluoroscopy etc...,
- Thoracic screws in deformities?

Low Profile,
Easy to use,
Adaptable.

- An implant associating the Postero Medial Translation effect of the Luque-type implant, without cutting through the bone,
- The **stability** of a **screw**,
- That would authorize any reduction/correction maneuvers,
- **Reduce the stress on the bone to allow an increase in reduction forces, especially for posteromedial translation of the thoracic spine.**

2000 – Spine Next

- Development of a dynamic stabilization implant for DDD (Wallis) with Pr Sénégas.
- ↳ First tests with flat polyester braids.

2001 – Spine Next

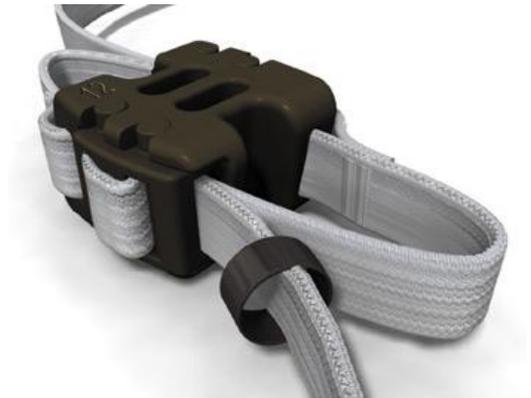
- Development of a full titanium system for large and progressive scoliosis reductions with Pr K. Mazda.

2002 – Spine Next

- Question : "*What if we merge both concepts?*"
- ↳ First use of a flat polyester braid in deformation reduction.
- ↳ First application filed in July 2002.

2004 – Spine Next

- On the day of first surgery with the **Universal Clamp** Abbott acquires Spine Next (UC not considered in the valuation).





Universal Clamp – 1st Gen – Dev. by Spine Next – Owned by Zimmer

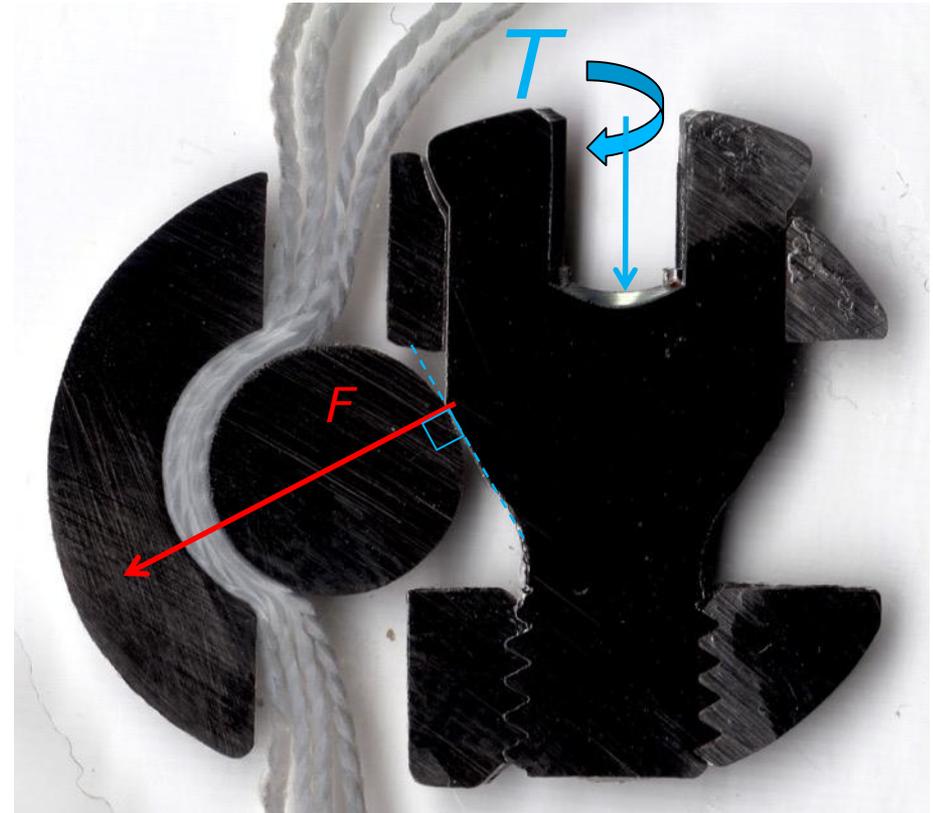
- A **polyester** band that can be locked on the rod,
- **Sublaminar** / interspinous / facet wiring / inter-transverse techniques,
- Allows **translation, distraction/contraction, in-situ bending** and rod **rotation**
- An **easy** to use, **low profile, flexible** and **reliable** solution



(Cuts of 80µm slice using a low speed diamond saw)

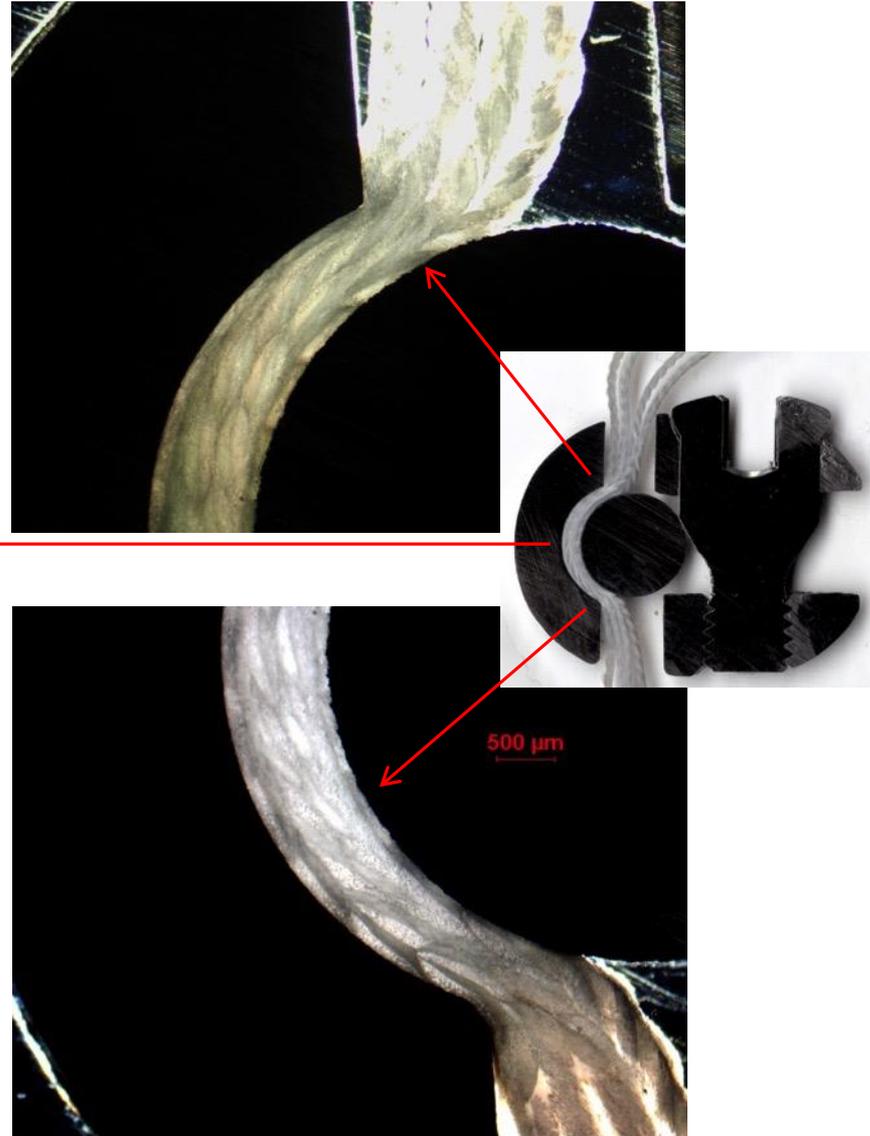
The torque applied to the screw is transformed into a compressive force applied to the band by means of the rod.

Under tension, the Jazz™ shows a uniform path.



Smooth Atraumatic Design
Chamfers to protect the band

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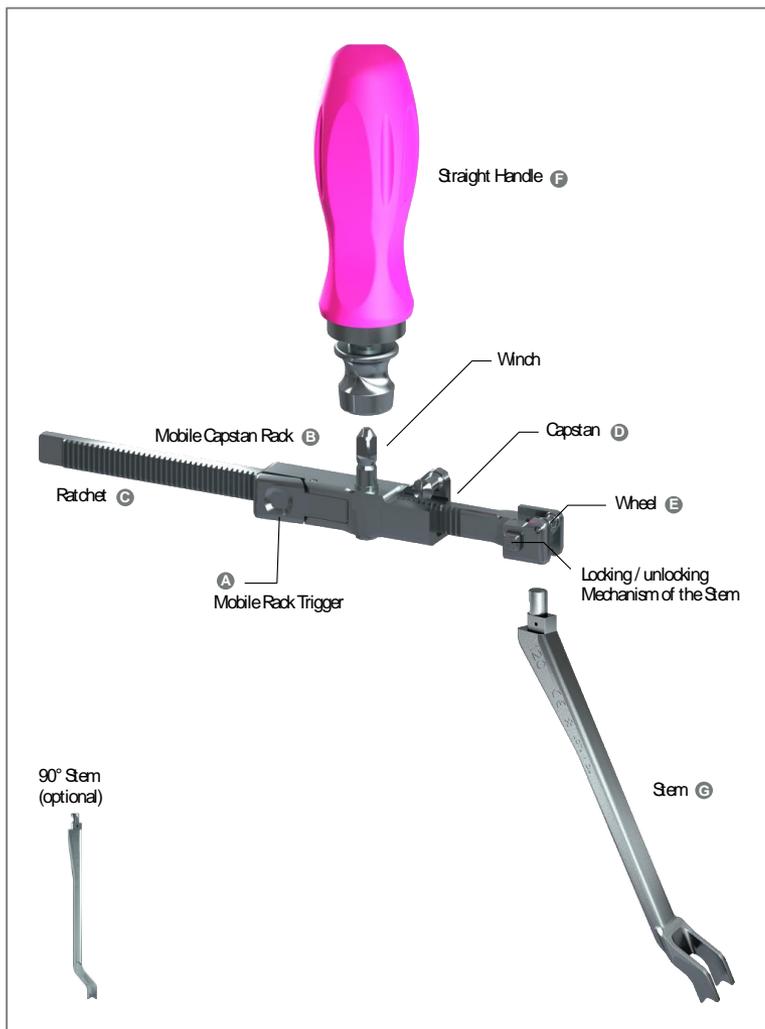


Pictures of a JAZZ™ specimen after a 350 N - 5 million cycle test.

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Key Instrument Band Tensioner



VS



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Product Positioning Statement

3.2. p.d. atitikimas: "Sterilioje pakuotėje."

The logo for Jazz™, featuring the word "Jazz" in a stylized, lowercase, pink font with a trademark symbol (™) to the right.

3.1. p.d. atitikimas: "Konektorius, kartu su sraigtu yra sterilioje pakuotėje"

The low profile sterile spinal Band fixation solution with the greatest clinical follow-up and amount of publications in adult and young patient treatments, illustrating its efficiency in an extensive range of degenerative, deformation and trauma pathologies, with the most comprehensive offering on the market covering thoraco-lumbar and cervical surgeries, featuring an optimized instrumentation, characterized by its ease-to-use, fast implementation, reduced inventory along with minimized cleaning/sterilization and logistic.

3. p.d. atitikimas: "Fiksacijos sistema indikuotina sublaminariams ir tarpslanksteliniams atvejams, tarpslankstelinio sąnario sujungimo technikoms, trauminėms stuburo operacijoms, degeneracinėms stuburo operacijoms, deformacinėms stuburo operacijoms."

Jazz™

Indications

3.1. p.d. atitikimas: "Konektorius vientisas, be judančių dalių"

The Jazz™ systems are temporary implants to be used in orthopedic surgery. The Jazz™ systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The Jazz™ systems are designed primarily for a posterior fixation. The indications for use include the following applications:

- Traumatic spinal surgery, use in sub-laminar and interspinous cases and in facet connection techniques.
- Surgery for spinal deformations such as scoliosis, kyphosis, lordosis, etc.
- Degenerative spinal surgery as a supplement to vertebral fusion, such as degenerative discopathy, stenosis, or spondylolisthesis.

The Jazz™ Systems may also be used in conjunction with other medical implants made of titanium alloy, unalloyed titanium or Cobalt-Chromium-molybdenum alloy to help secure the fixation of other implants.

3.1. p.d. atitikimas: "Galima rinktis tarp skirtingų konektorių, kurie pritaikyti fiksuoti sublaminarinę juostelę prie strypo vertikaliajoje arba horizontalioje padėtyje."



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Jazz™ Characteristics: Implanet Jazz™ System

Jazz™ provides a stable interface between spinal structure and the rod used in spinal surgery.

3.1. p.d. atitikimo paaiškinimas: konektorius matomas be judančių dalių.



Connector:

3.1. p.d. atitikimas: "Pagamintas iš titano lydinio"

- For 3.5, 4.0, 4.5, 4.75, 5.0, 5.5 and 6.0mm rods,
- Titanium: Ti6Al4V compliant with ISO 5832-3,
- Secure the band to the rod by a single locking screw in the connector

Connector Screw:



3.1. p.d. atitikimas: "Konektorius vientisas, be judančių dalių"



3.1. p.d. atitikimas: "Galima rinktis tarp skirtingų konektorių, kurie pritaikyti fiksuoti sublaminarinę juostelę prie strypo vertikaliaje arba horizontalioje padėtyje."

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Connector Diameter (= rod)	Diameter	Height
3.5 mm	6.5 mm	9.8 mm
4.0 mm	6.75 mm	10 mm
4.5 mm	7 mm	11 mm
4.75 mm	7.25 mm	12.2 mm
5.0 mm Evo	7.8 mm	11.5 mm
5.5 mm	7.8 mm	14.5 mm
6.0 mm	8 mm	14.5 mm



Connector Diameter (= rod)	Length	Width	Height *
3.5 mm	14 mm	8.5 mm	10 mm
4.0 mm	15 mm	8.75 mm	10 mm
4.5 mm	16 mm	9 mm	11 mm
4.75 mm	16.5 mm	9.25 mm	13 mm
5.0 mm Evo	17 mm	10 mm	12 mm
5.5 mm	17 mm	10 mm	15 mm
6.0 mm	17.3 mm	10 mm	15 mm

* height : screw inside the connector

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3.2. p.d. atitikimas: "Plokščia, pagaminta iš poliesterio..."

Jazz™ Band :

- Polyester band (polyethylene-terephthalate),
- **Flattened**, 700 mm braided band, 4 mm width and less than 0.5mm thick
- Allows tightening of the device **around** the **spinous** structures,
- **Malleable** stainless steel strip introduced and attached at one end of its tubular **extremity**:



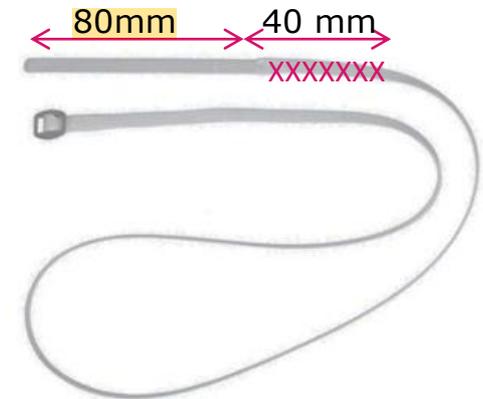
- Designed to facilitate passage of the band around bony structures during implantation. **NOT IMPLANTED.**

Stainless Steel Strip Dimensions:

- Length: 80 mm
- Width: 4 mm
- Thickness: 0.5mm

3.2. p.d. atitikimas: "... su 80 mm įsiūtu metaliniu galu."

- Back of the stainless steel strip, 40 mm ultrasonic welded band portion
 - Improves the maneuverability of the band
 - Can be cut before the 2nd pass in the connector

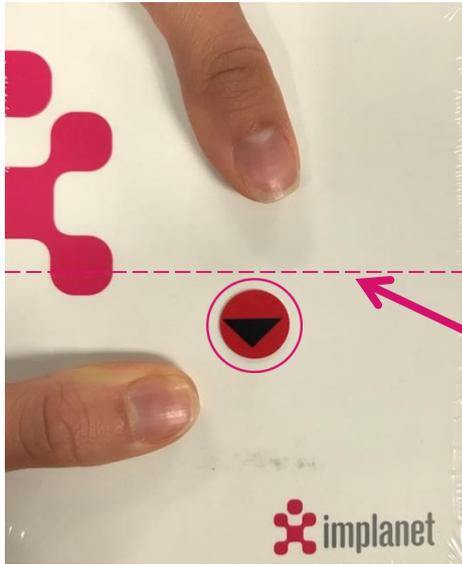


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3.2. p.d. atitikimas: "Juostelė gale turi metalinę sagtelę, skirtą juostelės užfiksavimui"

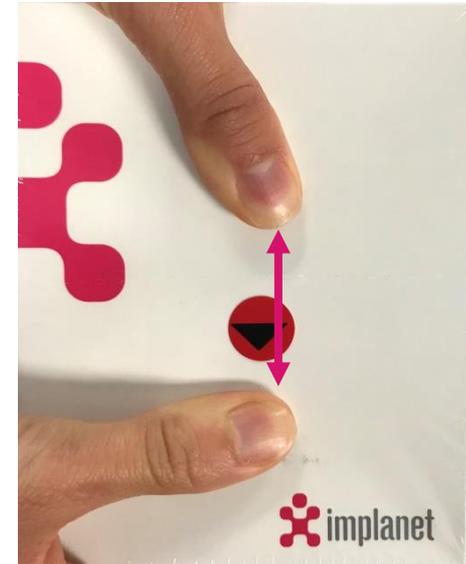
- A stainless steel buckle is attached at the other end (**not implanted**)
 - Connect both tips of the band to make a loop and to perform the tensioning of the band.
 - Dimensions:
 - Length 11 mm
 - Width 10 mm
- The **stainless steel elements** will be **removed** after the device and the band are finally secured,
- The **excess length** of the band is trimmed at **1 cm** from the top of the connector after the desired positioning of the device has been achieved.





Pre-cut lister for
an Easy Manual
Opening

Easy
Opening



3.2. p.d. atitikimas: "Sterilioje pakuotėje."



Reference #
Lot / Batch #
Expiration Date

Connector Kit Packaging



Color Code

3.1. p.d. atitikimas: "Konektorius, kartu su sraigtu, yra sterilioje pakuotėje"



Transparent or opaque
Connector+Screw

3.1. p.d. atitikimas: "Pakuotėje turi fiksuotą sraigą"





Jazz™

Passer

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An **additional option** of the Jazz™ Platform.
It assists the bands positioning
around the posterior structures of the spine.

The Jazz™ Systems are temporary implants to be used in orthopedic surgery. The Jazz™ Systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Jazz™ Systems may also be used in conjunction with other medical implants made of titanium alloy or cobalt-chromium-molybdenum alloy whenever «wiring» may help secure the attachment of other implants.



8 Passers divided in 3 types :

1. Straight
2. Round
3. Angled



1 Jazz™ Passer Band

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3.2. p.d. atitikimas: "Galima rinktis juosteles be įsiūto metalinio galo, bet su pravedimo skylė."

Universal

Jazz™ Passer can be used with all the Jazz™ Platform Connectors



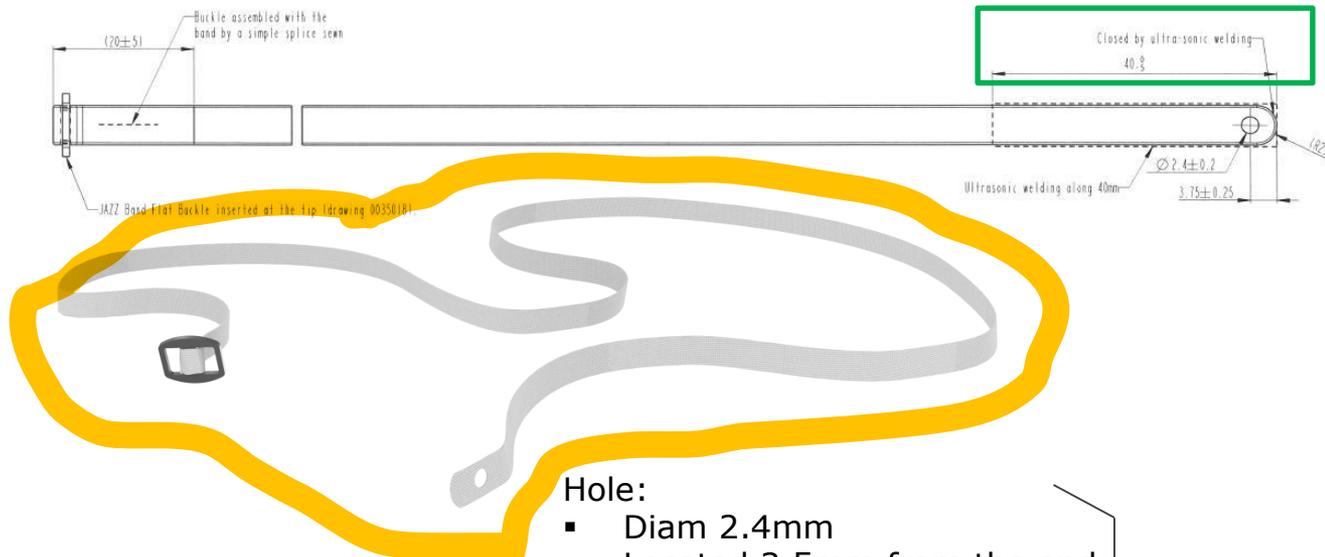
Simple

- No additional instrument tray required
- The 3 types of Passers integrated into existing Jazz™ Band trays
- A simple movement of the Passer handle passes the band around the anatomical structure

- 700 mm long
- 4 mm wide
- 40mm thermo-welded distal end
- Reduced thickness, 0.5 mm
- Equipped with a hole intended to receive the Passer Hook



3.2. p.d. atitikimas: "Galima rinktis juosteles be įsiūto metalinio galo, bet su pravedimo skykle."



Hole:

- Diam 2.4mm
- Located 3.5mm from the end



PREPARATION OF THE CONNECTOR Jazz™ / Jazz™ Claw / Jazz™ Lock / ...



The band is passed at first through the superior slot of the Jazz™ Band Connector taking care to first introduce the distal part.

Important!

It is not recommended to use a Jazz™ Band multipurpose Connector alone at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.

PASSAGE AROUND THE ANATOMICAL STRUCTURE

The selected Passer is introduced around the anatomical structure.



Step 1



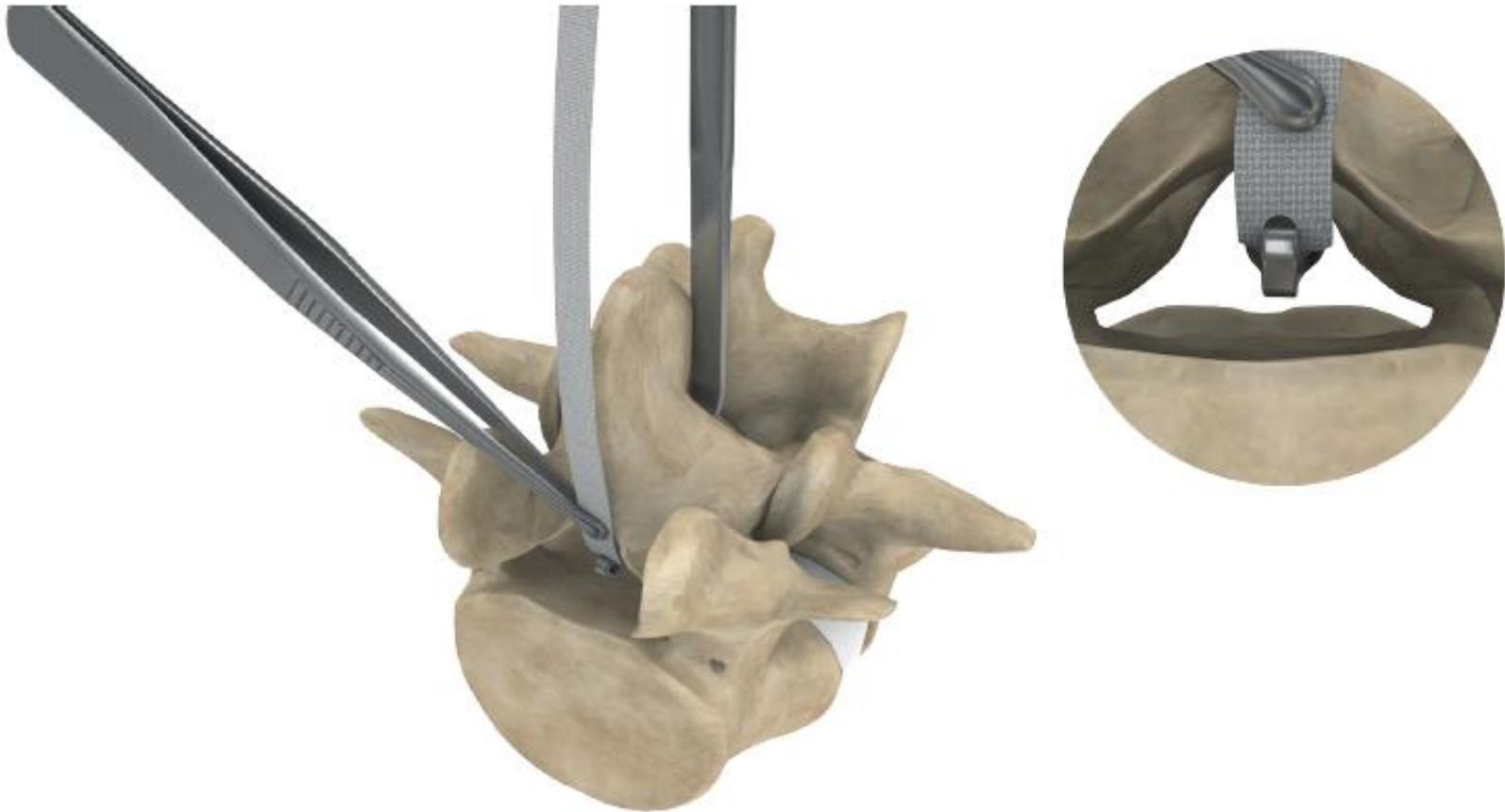
Step 2



Step 3

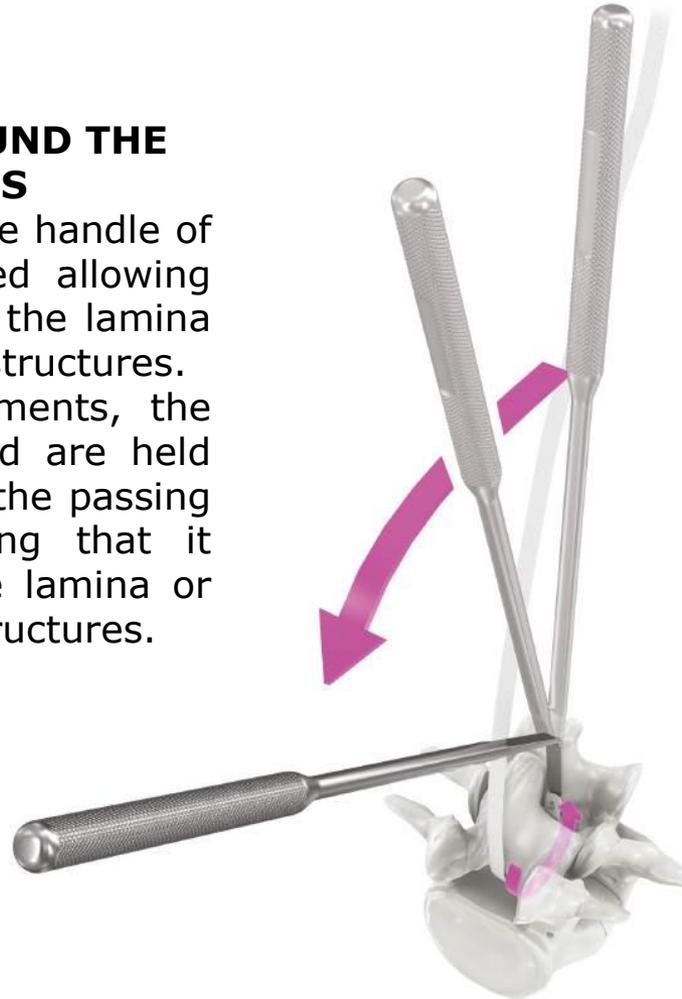
ATTACHING THE BAND TO THE PASSER

The band is introduced using the Braid Forceps. The Passer Band hole is placed around the hook of the Passer

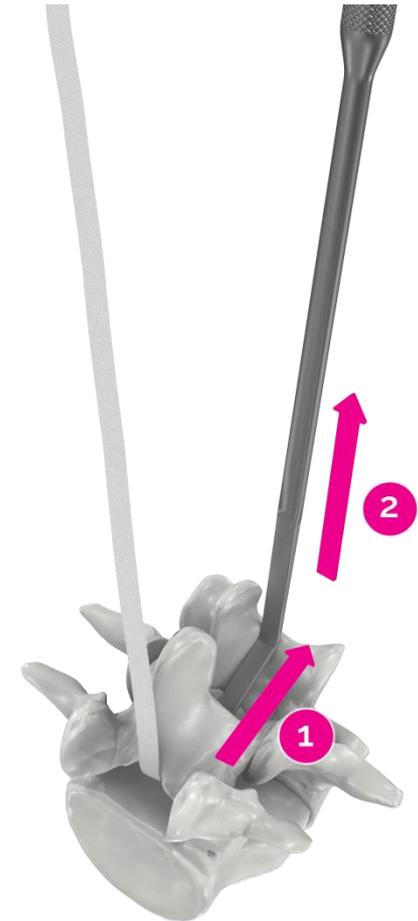


PASSING THE BAND AROUND THE ANATOMICAL STRUCTURES

Once the band is hooked, the handle of the Passer is slowly lowered allowing the band to progress under the lamina or around other anatomical structures. Using the dedicated instruments, the two extremities of the band are held and the surgeon completes the passing of the band while ensuring that it remains in contact with the lamina or with the other anatomical structures.



Round Passer

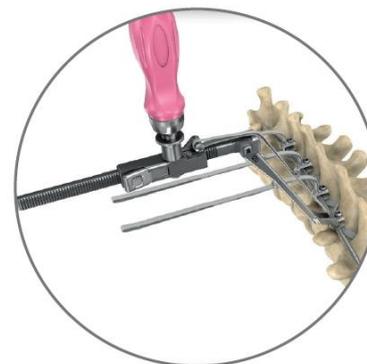


Straight Passer

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Refer to the Jazz™ operative technique for the following surgical steps:

- 2 band passages through the connector
- Closing of the band / Flat buckle – 3 passages
- Preparation of rods
- Connecting to the rods
- Jazz™ Band Tensioner
- Tensioner assembly
- Positioning the Tensioner and connecting the band
- Tensioning the band / reduction
- Distraction / compression maneuvers
- Final 2-in-1 locking of the screw



SECOND PASSAGE OF THE BAND THROUGH THE JAZZ™ LOCK CONNECTOR

Pass the distal end of the band back through the JAZZ™ Lock Connector.

This passage is from bottom to top, through the titanium base first.

Refer to the JAZZ™ Lock operative technique above for the following surgical steps:

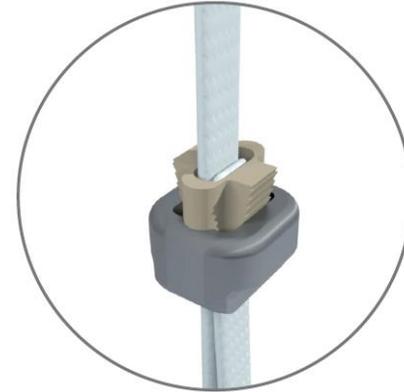
- Closing of the band
- Connector positioning and locking
- JAZZ™ Band Tensioner
- Connection to the band Tensioner
- Tension / Reduction of the band
- Tensioner and band assembly and positioning
- Tensioning

CUT THE BAND

Once the final positioning of the JAZZ™ Band Connector, the JAZZ™ Claw Connector, or the JAZZ™ Lock Connector is achieved, the excess band is cut at about 1cm from the Connector.

Important !

The buckle (proximal part of the band) and the distal part of the band must **IMPERATIVELY** be removed. These components are considered temporary instruments that must **NOT** be implanted. Please note that for each step of this surgical procedure, it is recommended to only use specifically designed instruments from the JAZZ™ System ancillary range.





Jazz™ Passer Band

150157 *Jazz Passer Band*



Straight Passer

REFERENCE DESIGNATION

550341 *Straight Passer - 15 mm*

550342 *Straight Passer - 20 mm*

550343 *Straight Passer - 25 mm*

550350 *Straight Passer - 30 mm*



Round Passer

550344 *Round Passer*



Large Round Passer

550349 *Large Round Passer*



Round Passeur R20

550351 *Round passer R20*



Round Passer Angled

550345 *Round Passer - Angled*



Jazz Elevator

726-7514-0 *JAZZ Elevator*



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