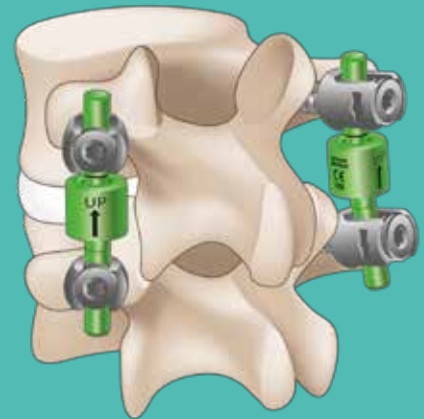
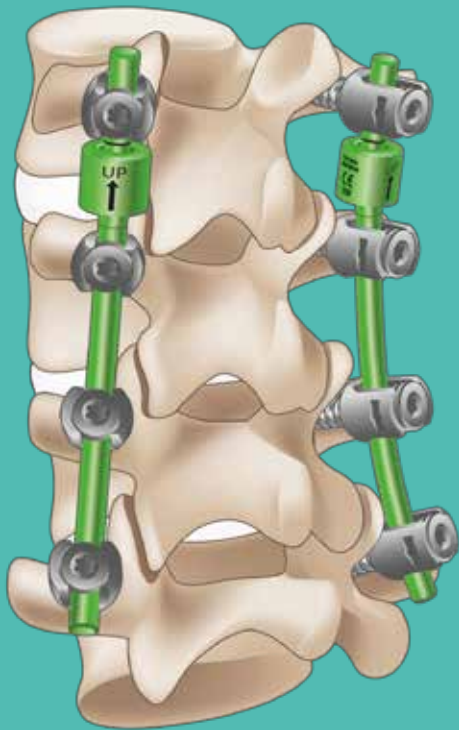


BDyn

Spinal dynamic posterior
stabilization device



We care for Surgery

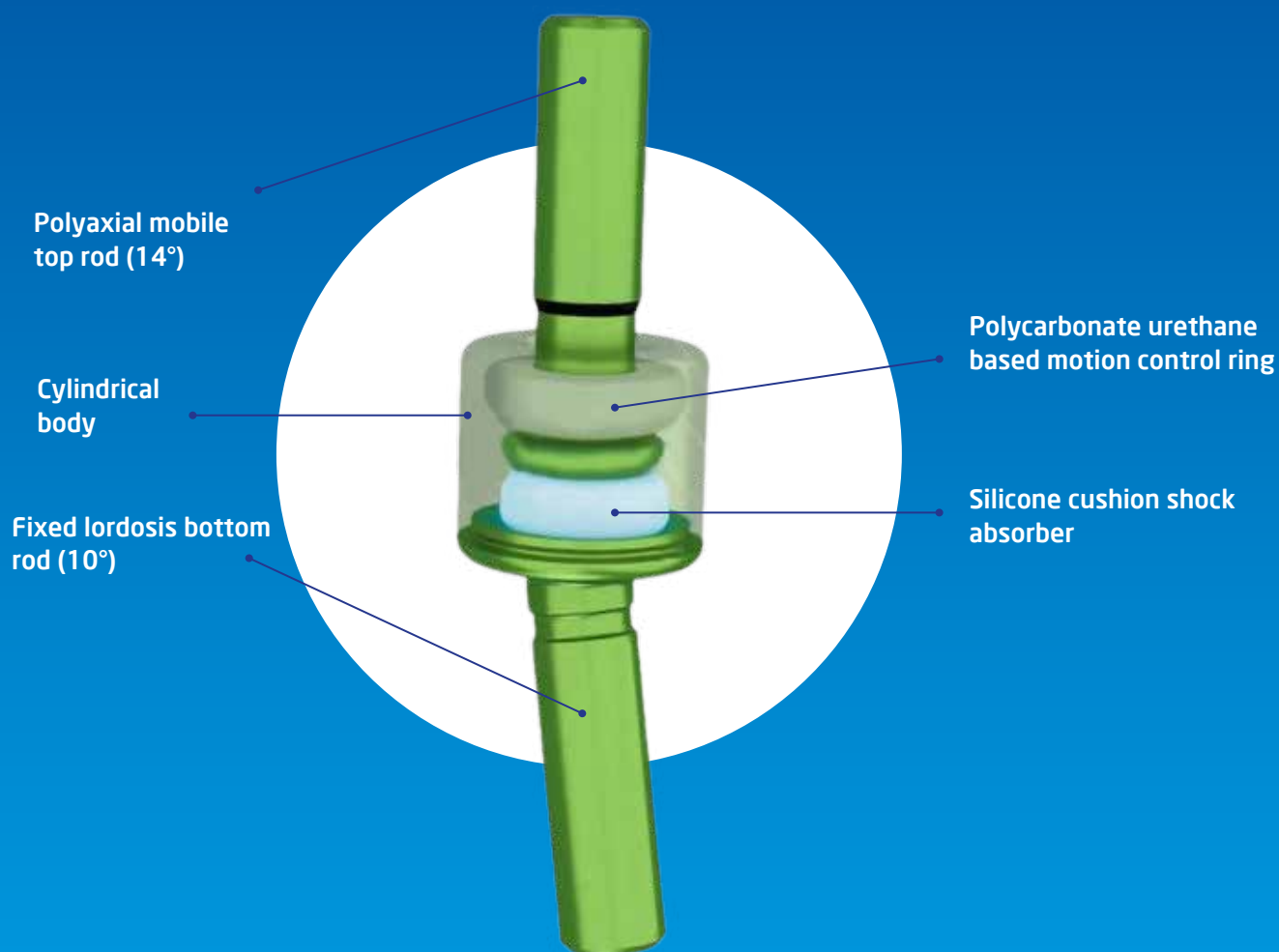
Surgical technique

BDyn

Spinal dynamic posterior stabilization device

PRODUCT DESCRIPTION

The sterile spinal dynamic posterior stabilization device BDyn is intended to restore the stabilization of the non-cervical segment of the spine by preserving the anatomical lordosis and the deadening of the intervertebral joint. It is composed of the BDyn spinal shock absorber fixed on the vertebrae thanks to the dedicated screws.



THE STERILE SPINAL DYNAMIC POSTERIOR STABILIZATION DEVICE BDYN IS COMPOSED OF:

BDYN IMPLANT

The spinal shock absorber is available in several sizes:

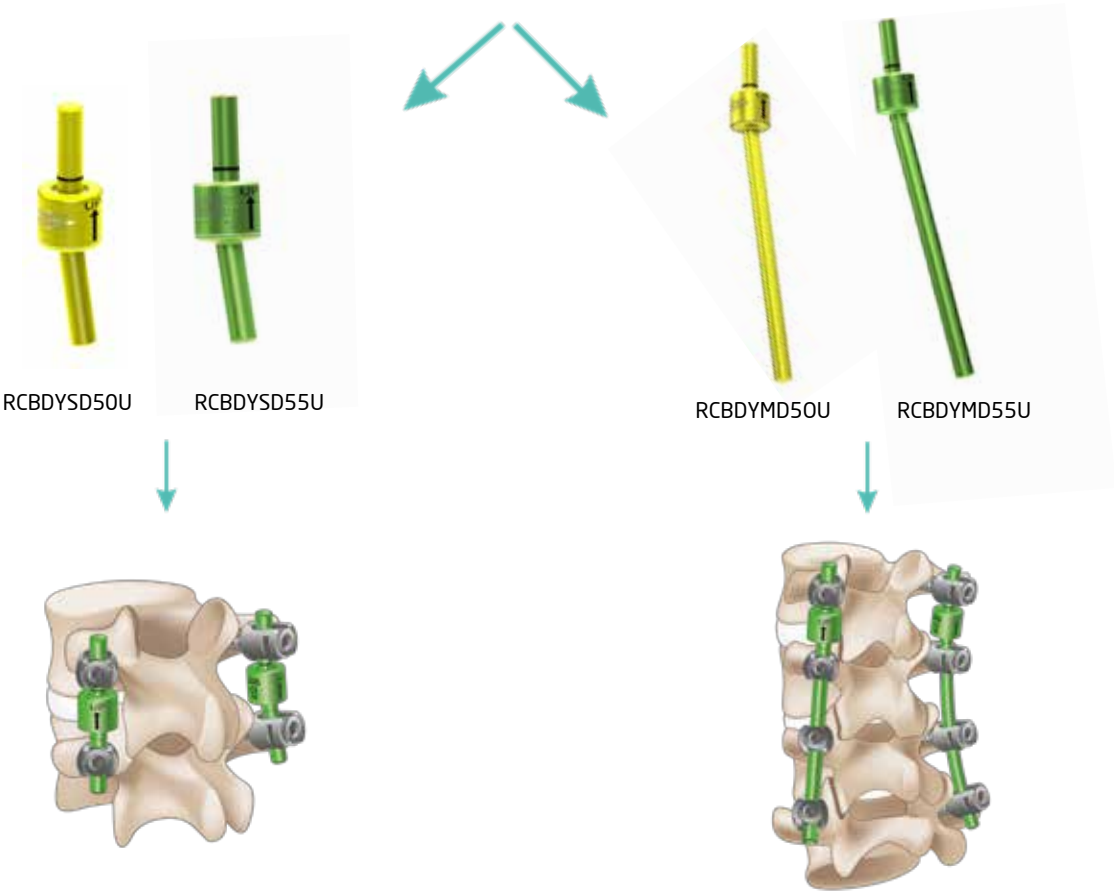
Size of BDyn	Diameter of rod	Reference
Small (47 mm)	5.0 mm	RCBDYSD50U*
Medium (107 mm)	5.0 mm	RCBDYMD50U**
Small (47 mm)	5.5 mm	RCBDYSD55U*
Moyen (107mm)	5.5 mm	RCBDYMD55U**

**Small BDyn references can be used with 4 pedicle screws*

***Medium BDyn references can be used with 6 or 8 pedicle screws for one or two fusion levels respectively. Indeed, the fixed rod can be cut for a single level of fusion at the surgeon decision.*

For more information on compatible screws, please refer to the IFU.

A DYNAMIC POSTERIOR STABILIZATION SYSTEM CONSIST OF:



BDYN ROD AND SCREWS ANCILLARIES



SQUARE AWL
014112C



THORACIC PERFORATOR
RCBANTPERU



LUMBAR PERFORATOR
RCBANLPERU



REVERSIBLE SOUNDER
RCBANSOUNU



BALL SOUNDER
016103



KIRSCHNER WIRE
911537



CANNULATED TAP 5.0MM
013615



CANNULATED TAP 6.0MM
013616



ROCKER
011300



CANNULATED SCREWDRIVER
010201C



TRIAL IMPLANT TD50
RCBANTD50U



BDYN HOLDER
RCBANBDHOU



ROD PUSHER
RCBANRODPU



ROD HOLDER
RCBANRH50U



ROD BENDER
RCBANLRBEU



PERSUADER
011308



SET SCREW DRIVER
010505C



SET SCREW HOLDER
010494



DISTRACTOR FORCEPS
RCBANDISTU



COMPRESSOR FORCEPS
RCBANCOMPU



COUNTER TORQUE
010610C



DYNAMOMETRIC HANDLE
RCBANDH10U



CANNULATED T-HANDLE WITH RATCHET
010001N



CANNULATED STRAIGHT HANDLE WITH RATCHET
013001N

INDICATIONS

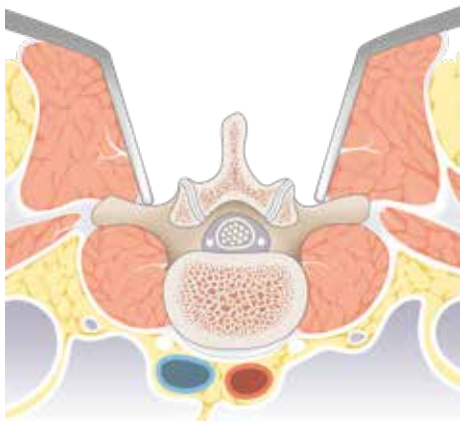
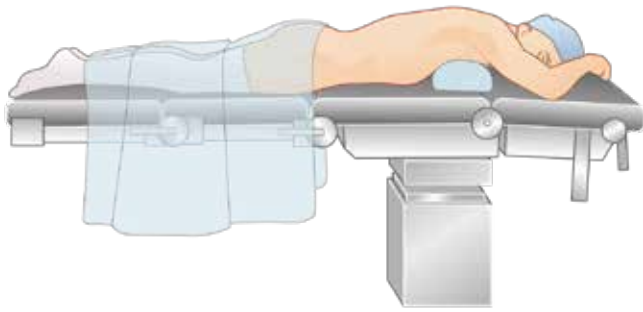
The sterile spinal dynamic posterior stabilization device BDyn is intended for posterior stabilization from thoracic vertebrae T10 to sacrum S1 with or without bone graft for the following indications:



- » Degenerative intervertebral disc disease and/or articular facets confirmed by further examinations
- » Spinal canal stenosis
- » Degenerative spondylolisthesis grade 1
- » Segmental instability

CONTRAINDICATIONS

- » Active infectious process or significant risk of infection (immunocompromise)
- » Signs of local inflammation
- » Fever or leukocytosis
- » Morbid obesity
- » Pregnancy
- » Mental illness
- » Grossly distorted anatomy caused by congenital abnormalities
- » Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of the sedimentation rate unexplained by other diseases, elevation of the white blood count
- » Suspected or documented metal allergy or intolerance
- » Any case where the implant components selected for use would be too large or too small to achieve a successful result
- » Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- » Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- » Any patient unwilling to follow postoperative instructions
- » Any case not describe in the indications
- » Traumas (i.e. fracture or dislocation)
- » Abnormal curvatures (i.e. scoliosis and/or hyper lordosis)
- » Tumors
- » Spondylolisthesis grade 2 and more
- » Pseudarthrosis and/or failed previous fusion
- » Severe bone resorption, osteomalacia, severe osteoporosis



1 POSITIONING

Prone position under global or regional anesthesia.
The affected level is monitored by X-Ray.

2 INCISION

Incision on the midline on the outer edge of the spinous processes. The muscles are laterally retracted from spinous processes.

3 PREPARATION

Use of the square awl (014112C)

Prepare the entry point at the cortical bone with the help of a square awl



Use of the thoracic perforator (RCBANTPERU) and lumbar perforator (RCBANLPERU)

Perforate pedicles. Two perforators are available:

- Lumbar perforator



- Thoracic perforator



Pedicle palpation (RCBANSOUNU ou 016103)

The scale on the probe allows the surgeon to estimate the length of the screws to be implanted.

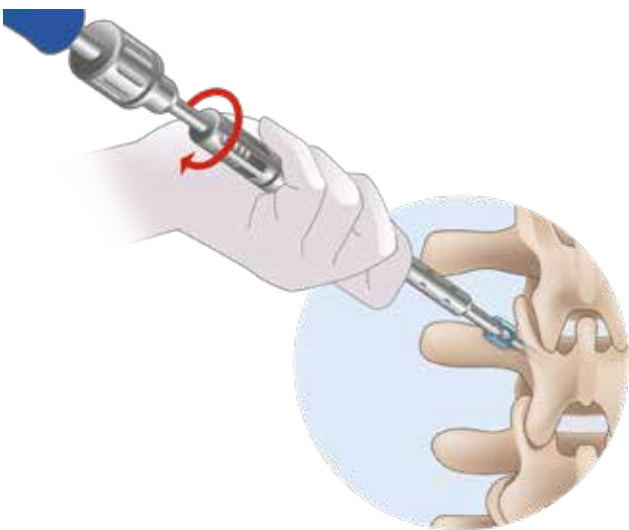
Two probes are available:

- Reversible sounder (RCBANSOUNU)



- Ball sounder (016103)





Tap (013615 ou 013616)

If the surgeon use non self-tapping screws, a tap is available. The tap is clicked on the cannulated handle.

Two tap diameters are available:

- Tap diameter 5.0mm (013615)
- Tap diameter 6.0mm (013616)



All instruments and self-tapping screws are cannulated to allow the use of Kirschner wires.

Use a Kirschner wire to guide the self-tapping screw and ensure the right positioning of the screw in the vertebra

4

INSERTION OF PEDICLE SCREWS

The diameter and the length of the screw are determined by the surgeon.

The rocker (011300) is used to hold the polyaxial screw by its head.

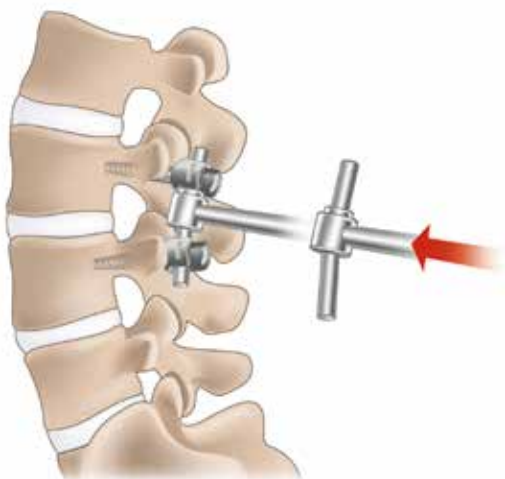


Click the straight cannulated handle on the polyaxial screwdriver (010201C) then assemble it on the polyaxial screw.

Slide the straight handle - screwdriver - polyaxial screw assembly onto the Kirschner wire

The screws are placed laterally to the facet joint.

Once the screw is in place, pull on the Kirschner wire to remove it, then release the gripper screw by unscrewing the knob.



5 USE OF THE TRIAL IMPLANT

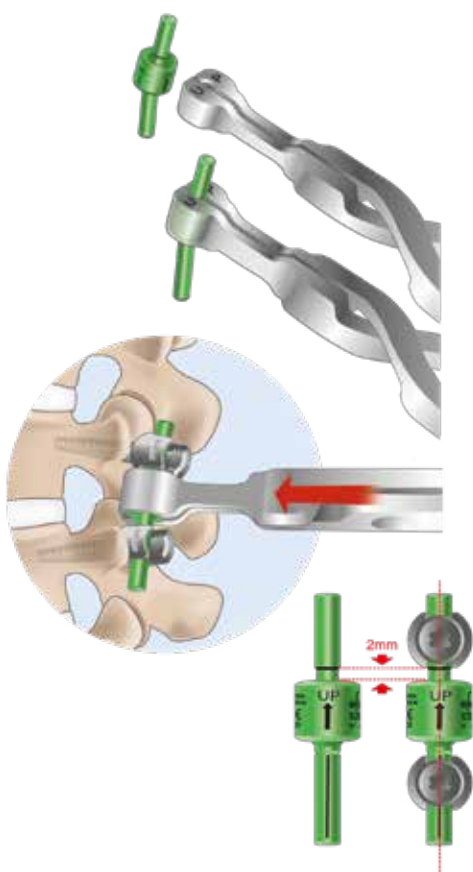
The trial implant TD50 (RCBANTD50U) enables to better estimate the spare requirement of the Bdyn dynamic rod and optimise the implantation of screw.



The BDyn device must maintain its alignment in the frontal and sagittal planes with the cylindrical body and its 2mm shock absorption reserve for optimal in situ operation of the device.

It's possible to re-adjust the height of the screw by using the screwdriver.

If there is not enough space for the cylindrical body, it is possible to remove part of the bone from facet joint.



6 BDYN DYNAMIC ROD POSITIONING

Positioning the BDyn dynamic rod (RCBDYSD55U or RCB DYMD55U or RCB DYSD50U or RCB DYMD50U) into the heads of polyaxial screws with the help of the BDyn holder (RCBANDHOU) and precisely adjust the position of the polyaxial top mobile rod of BDyn dynamic rod.



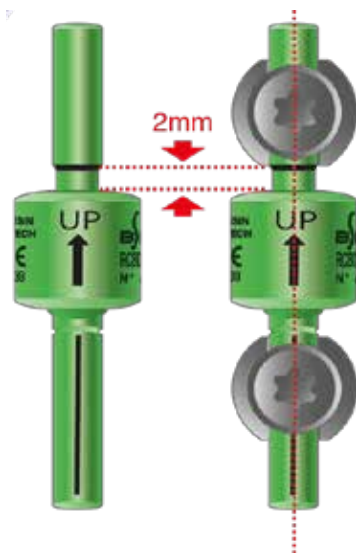
Take the BDyn device, observing the «UP» direction and the alignment of the arrow between the jaws of the BDyn holder.

It should strictly keep a reserve of 2mm between the top of the cylindrical body and the lower part of the screw head, in order to have an optimal dynamic behavior.

If the surgeon decides not to use the BDyn device and proceeds with a fusion, a rod holder (RCBANRH50U) is available.



Medium BDyn references can be used with 6 or 8 pedicle screws for one or two fusion levels respectively



It should strictly keep a reserve of 2 mm between the top of the cylindrical body and the lower part of the screw head, in order to have an optimal dynamic behavior.

In order to ensure the correct disc height and the 2mm shock absorption reserve, the screw heads can be repositioned on the rod using the distraction (RCBANDISTU) or compression forceps (RCBANCOMPU).

The bottom of the upper screw head must be positioned on the laser marking to guarantee these 2mm. The arrow must be aligned with the 2 screw head opening.



First tighten using the set screw holder (010494)

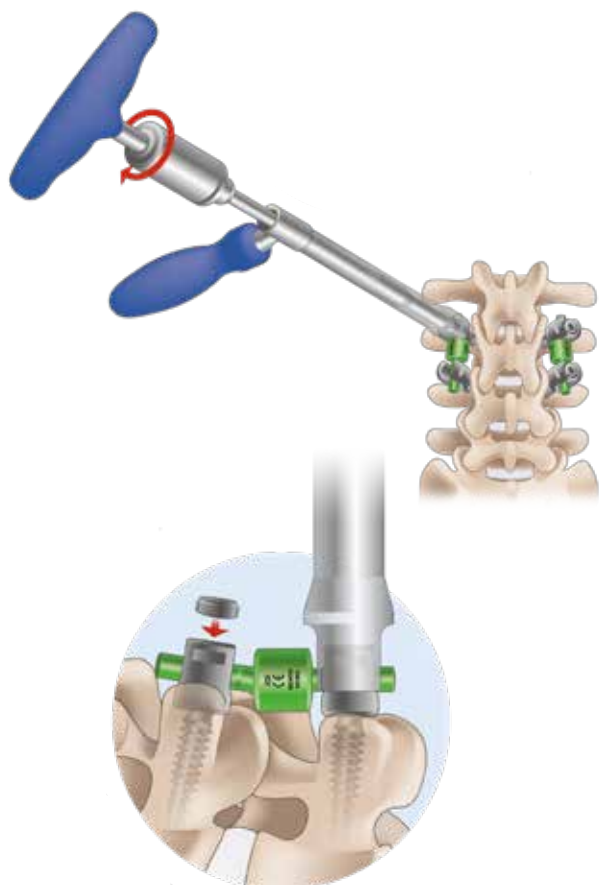


In the case of long constructs, a rod bender is available to bend the lower part of the BDyn rod.



In order to maintain the BDyn device at the bottom of the polyaxial screw heads:

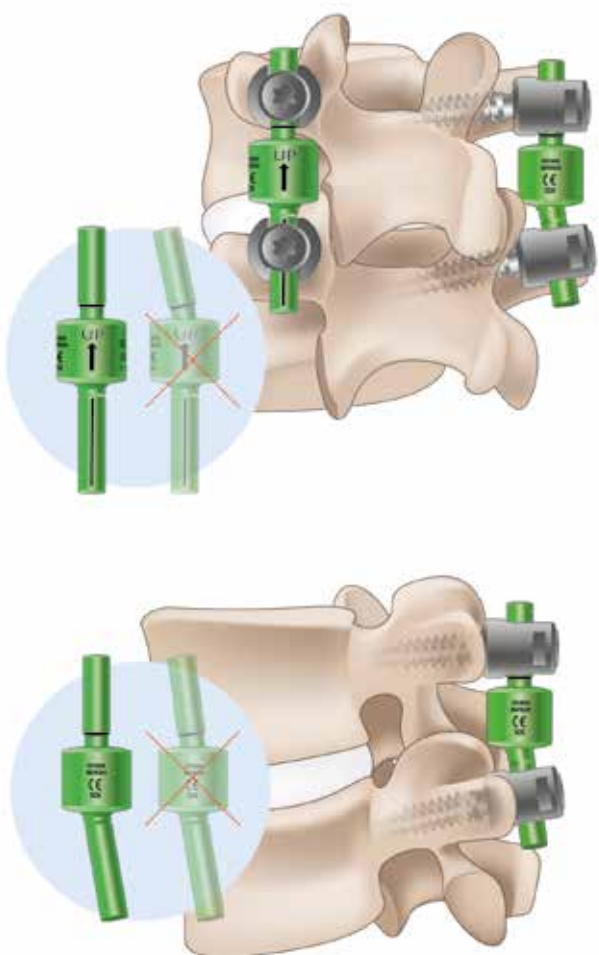
- A rod pusher (RCBANRODPU) is available for short constructs
- A persuader (011308) is available for long constructs requesting more strength to maintain the device.



7 FINAL TIGHTENING OF SET SCREWS

Use the dynamometric handle associated to the set screw driver (010505C) for final tightening of set screws.

Using the counter torque (010610C) facilitates the final tightening and guarantees the 2mm shock absorption reserve required for the BDyn device to operate correctly.



8 ASSEMBLING INSPECTION

Check the assembling with x-rays.

The BDyn must always maintain its original profiles.

The polyaxial BDyn top mobile rod must maintain:

- Its alignment in the frontal and sagittal plane with the cylindrical body.
- The shock absorption reserve of 2mm for an optimum in-situ function of the device.



Keep the original alignment of the implant.

Keep the shock absorption reserve of 2mm.

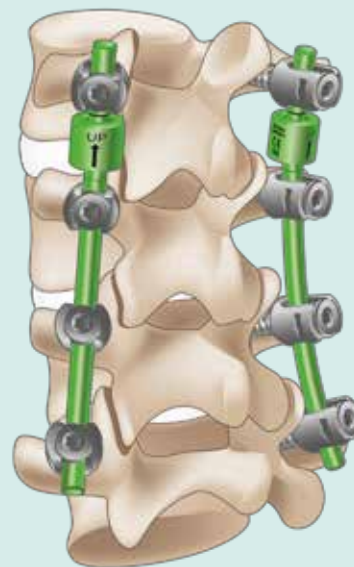


In case of mis-alignment of the mobile rod, the surgeon can realign it by using the counter torque to turn the head of the screw in the access of the cylindrical body.

9 FINAL ASSEMBLING



➤ **Final assembling of the BDyn - Small**
Réf : RCBYSD55U - RCBYSD50U



➤ **Final assembling of the BDyn - Medium**
Réf : RCBYMD55U - RCBYMD50U

- 1 Remove the screw caps using the screwdriver provided by the manufacturer of the screws used, having previously placed the counter torque on the screw heads.
- 2 Once all the screw caps have been removed (on one side, then on the other), proceed to the removal of the rods.
- 3 Now that the rods are removed, using the supplied screwdriver, proceed to the removal of the screws.

After the explantation procedure, Cousin Surgery does not have the capacity to indicate the next steps in the case of a revision surgery.



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BDyn implant is a class IIb medical device. The BDyn instrument kit is composed of class I instruments medical devices manufactured by COUSIN BIOTECH S.A.S & Neuro France Implants. The CE conformity has been carried out by the notified body SGS Belgium NV (CE1639).

The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard. Please read carefully the instructions for use before using the device. The IFU is available electronically at: <https://www.cousin-biotech.com/en/implant-notice>

Reference: TORBDCGB01 - Version: 07/12/23. Non contractual pictures and texts. Specifications likely to be modified without notice.

Cousin Biotech S.A.S capital : 340 656 € • 398 460 261 RCS Lille • N°TVA FR 34 398 460 26

Cousin Biotech is the legal manufacturer of the medical devices proposed by Cousin Surgery.