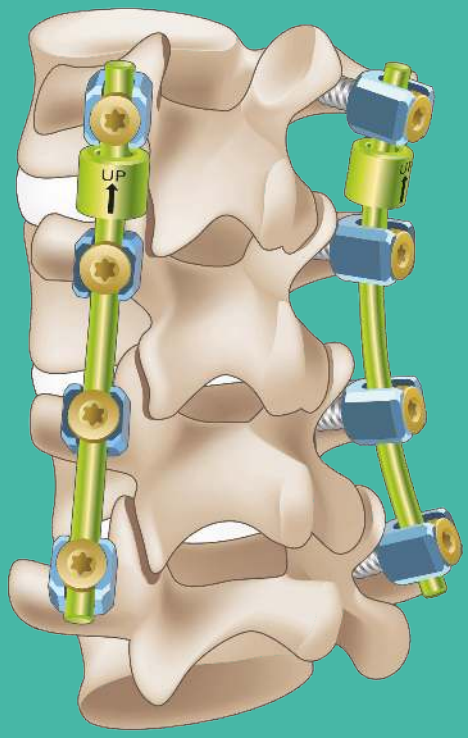
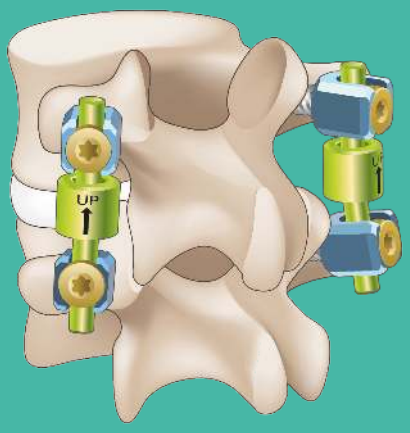
COUSIN SURGERY

BDyn

Spinal dynamic posterior stabilization device





We care for Surgery

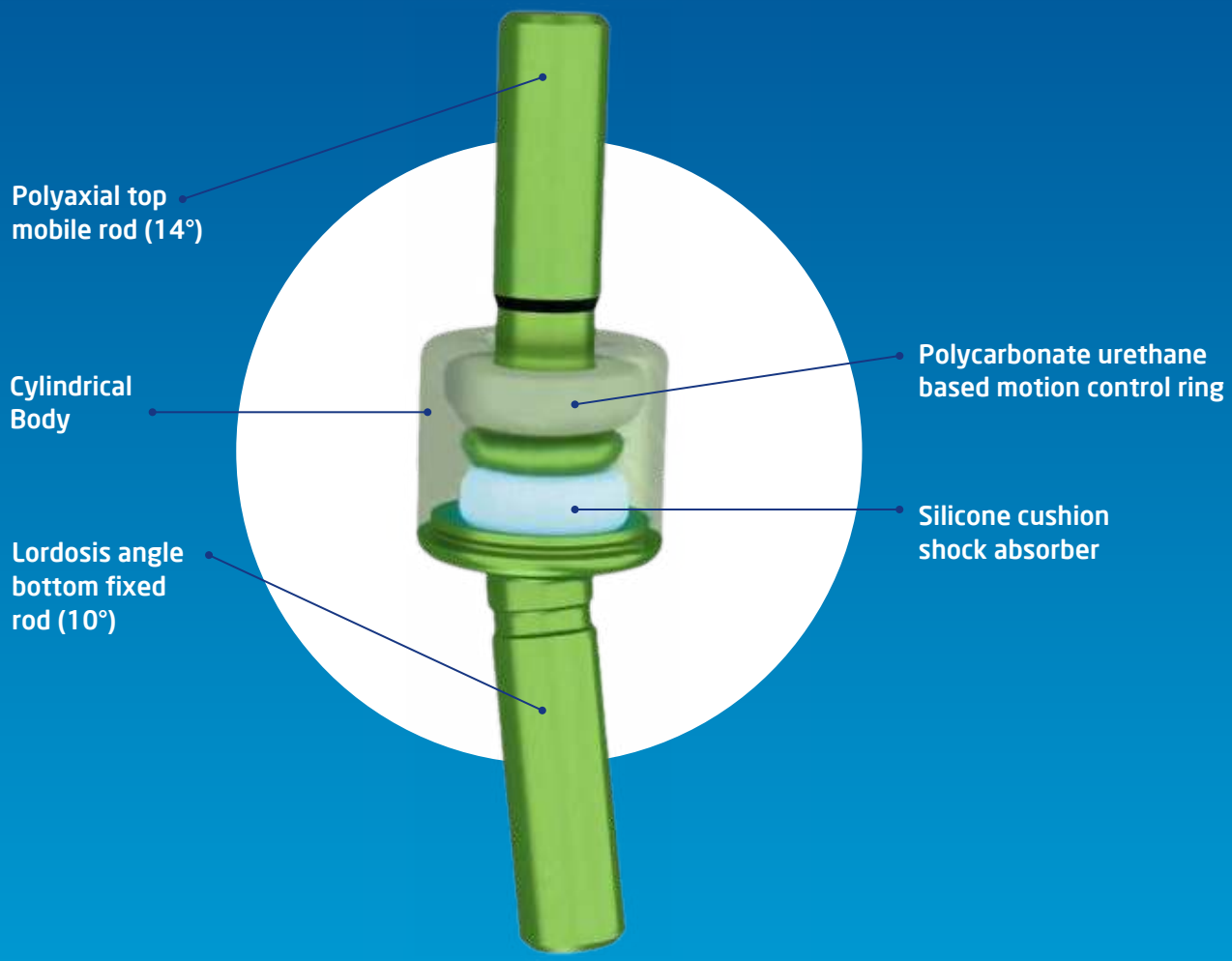
Surgical Technique

BDyn

Spinal dynamic posterior stabilization device

PRODUCT DESCRIPTION

The sterile spinal dynamic posterior stabilization device BDyn is intended to restore or to preserve, as long as possible, the normal stabilization of the segment of the spine from the thoracic vertebra T10 to the sacrum S1 by maintaining the anatomical lordosis and supporting the shock absorption of the intervertebral discs.



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

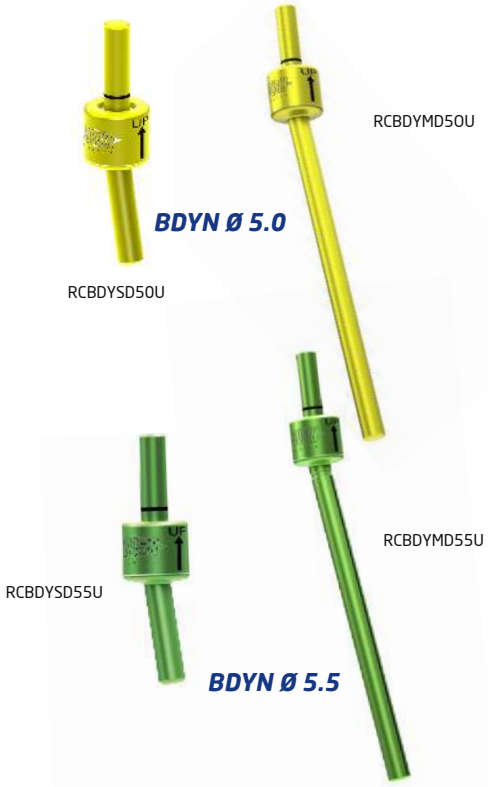
BDYN IMPLANT

The spinal shock absorber is available in several sizes:

Size of BDyn	Diameter of rod	Reference
Small	5.0 mm	RCBDYSD50U
Medium	5.0 mm	RCBDYMD50U
Small	5.5 mm	RCBDYSD55U
Medium	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.*



BDYN ROD SPECIFIC ANCILLARIES



TRIAL PROSTHESIS IMPLANT
RCBANTD50U



BDYN HOLDER
RCBANBDH0U

INSTRUMENTS - SCREWS

Use the appropriate instruments for the screws used, i.e the counter torque.

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

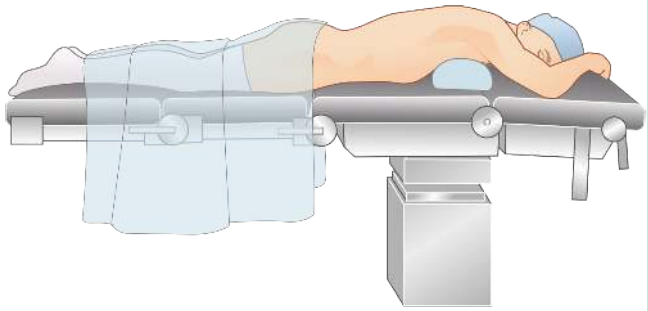
› Spinal canal stenosis

› Degenerative spondylolisthesis grade 1

› Segmental instability

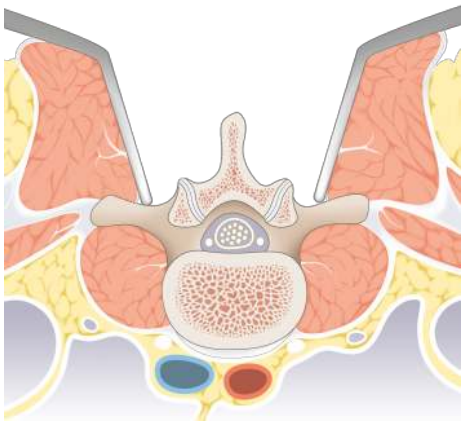
CONTRAINDICATIONS

- 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



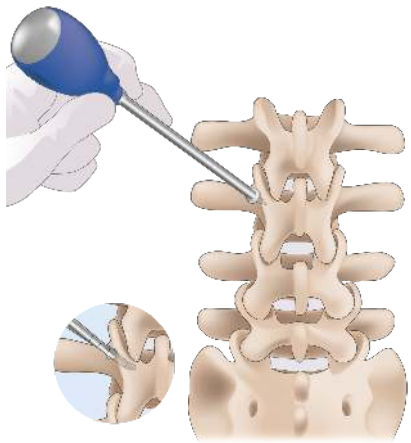
1 POSITIONING

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



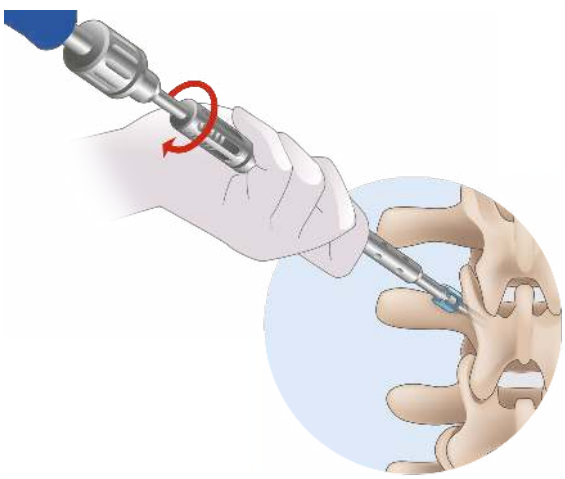
2 INCISION

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



3 PREPARATION

Prepare the entry point at the cortical bone with the help of a square awl.
Use perforators and spatula to create the channel for the screw.
With a sounder, the surgeon will ensure the good pedicular preparation. To improve the optimal passage of the pedical screw use a standard tap according the screw diameter.

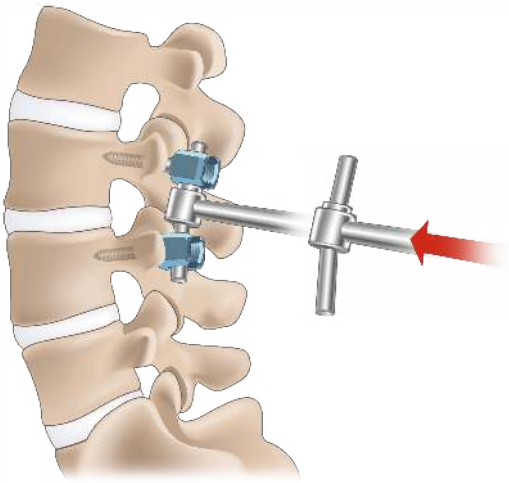


4 INSERTION OF PEDICLE SCREWS

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

Use the standard surgical technique corresponding to the chosen screws.

The screws are placed laterally to the facet joint.



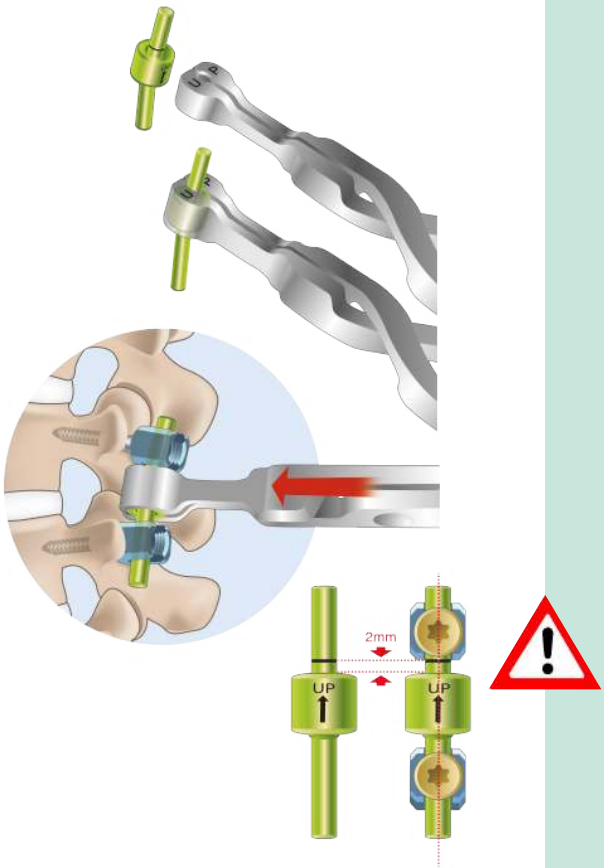
5 USE OF TRIAL PROSTHESIS

It is necessary to optimize the location of polyaxial screw in order to facilitate the positioning of BDyn device.

The Trial Prosthesis TD50 BDyn (RCBANTD50U) enables to better estimate the bulk of the BDyn dynamic rod and optimise the implantation of screw. It must be perfectly flattened against the bottom of polyaxial screws heads without affecting articular facets.

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

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



6 B-DYN DYNAMIC ROD POSITIONING

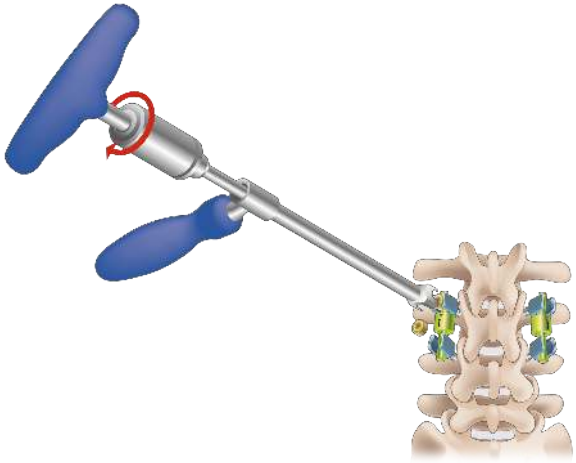
The upper jaws of the BDyn holder (RCBANBDHOU) must be positionned exactly on the black mark of the polyaxial rod.

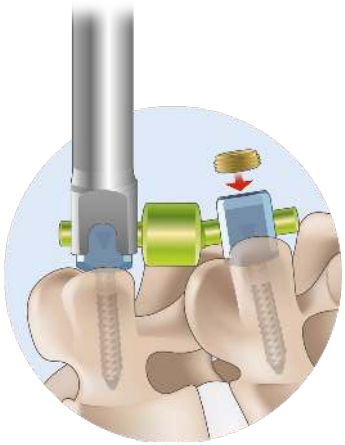
Positioning the BDyn dynamic rod into the heads of polyaxial srews with the help of the BDyn holder (RCBANBDHOU) and precisely adjust the position of the polyaxial top mobile rod of BDyn dynamic rod.

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. The bottom of the upper screw head must be positionned on the laser marking to guarantee this 2mm.

The arrow must be aligned with the two screw head opening.

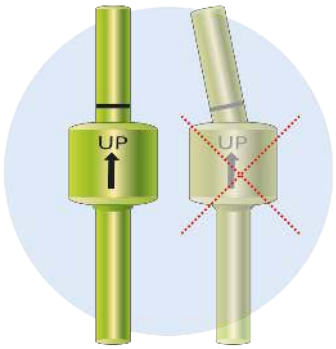
Perform a pre-tightening of polyaxial screw plug with a standard setscrew holder.

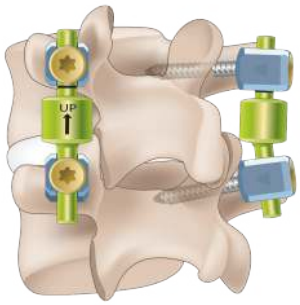


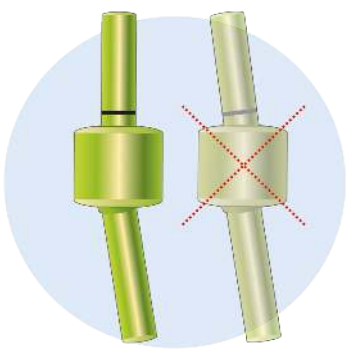


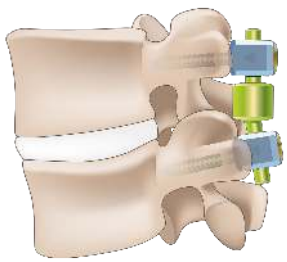
7 FINAL LOCKING OF TIGHTENING PLUGS

Use the counter torque and final tightening shaft corresponding to the chosen screws according the screw surgical techniques.









8 ASSEMBLING INSPECTION

Check the assembling with radiographies.

The BDyn must always maintain its original profiles.

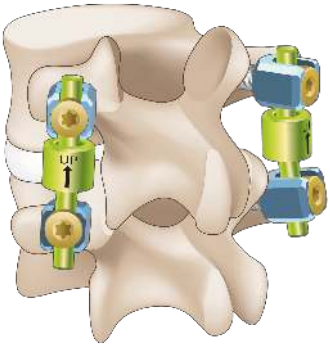
The polyaxial BDyn top mobile rod must maintain:

- its alignment in the frontal and sagittal plane with the cylindrical bodies
- the depreciation reserve of 2mm for an optimum in-situ function of the device.

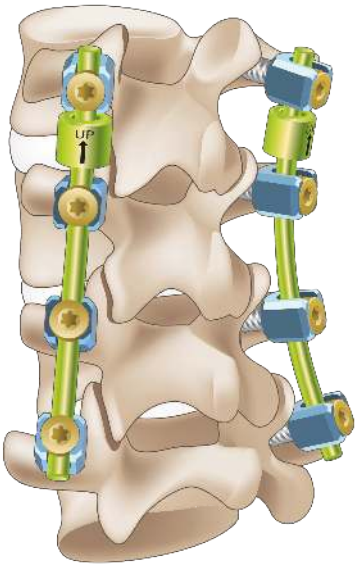
Keep the original alignment of the implant.

Keep the shock absorption reserve of 2 mm.

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.



› **Final assembling of the BDyn - Small**
Ref: RCBDYSD55U - RCBDYS50U



› **Final assembling of the BDyn - Medium**
Ref: RCBDYMD55U - RCBDYMD50U

9 FINAL ASSEMBLING

STEPS 3 TO 8 ARE REPEATED FOR THE IMPLANTATION OF A SECOND BDYN DEVICE.

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.

NOTES

NOTES

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Allée des Roses • 59117 Wervicq-Sud • FRANCE

BDyn implant is a class IIb medical device and BDyn ancillaries are a class I medical devices manufactured by COUSIN BIOTECH S.A.S. 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-notices

Reference: TORBDYGB04 - Version: 22/09/22. 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 offered by Cousin Surgery.