

(English) TELESCOPIC PLATE SPACER (TPS™) SPINAL SYSTEM, CERVICAL

INDICATIONS FOR USE

The **Biomet Telescopic Plate Spacer (TPS)** Spinal System implants are intended to replace normal body structures following a corpectomy of the spine in patients with tumors, traumatic fractures, one to two level stenosis, and ossification of the posterior longitudinal ligament. The **TPS** Spinal System implants are intended to correct spinal alignment and stabilize the spinal operative site during fusion. **TPS** Spinal System implants attach to the spine anteriorly by means of their trapezoidal shape and by screws joined with a plate and spacer component.

PRODUCT DESCRIPTION

The **Biomet TPS** Spinal System implants function as a single construct that combines an anterior plate and an intervertebral column spacer. The **TPS** Spinal System implants are composed of seven components. The device consists of one (1) female chamber, one (1) male chamber, one (1) set screw and four (4) bone screws. The **TPS** Spinal System implants are made from medical implant grade titanium alloy as described by ASTM Standard F-136 (Ti 6Al-4V ELI) and are available for one and two level corpectomies. A one level cervical corpectomy device telescopes in length from 22.3mm to 29.4mm; a two level cervical corpectomy device telescopes in length from 33.5mm to 49.8mm.

INSTRUCTIONS FOR USE

SURGICAL TECHNIQUE:

After appropriate patient selection criteria has been applied and informed consent has been rendered, the following surgical technique will apply:

1. Standard anterior Cloward approach for tumors at C4-C7, or modified Cloward approach for the cervico-thoracic junction T1-T2, or for tumors at C3 an extra-pharyngeal (McDonnell) approach is recommended to expose the surgical level.
2. X-ray or fluoroscopy to confirm the surgical level.
3. Place the retractors beneath the longus colli muscles.
4. Perform corpectomy at the diseased level(s) with a discectomy above and below the corpectomy. Use the available templates to gauge the width of the corpectomy defect, seen in the A/P view, to ensure the corpectomy is wide enough to accept the male and female chambers.
5. Remove the cartilaginous end plates, but preserve the cortical end plate of the adjacent vertebrae.
6. Fill the male component of the **TPS** device with allograft cancellous bone.
7. Assemble the male and female components to a length which closely approximates the corpectomy defect, and finger tighten the set screw. The set screw will draw the teeth of the male component to the teeth of the female component, maintaining the desired device length.
8. Continue filling the assembled device with allograft cancellous bone.
9. With the distractor, place the **TPS** device into the corpectomy defect with the male chamber cephalad and the female chamber caudal. Ensure that the flanges of the device are flush on the adjacent vertebrae. A distractor pocket is provided in the bone flanges of the male and female chamber. The distractor uses the pockets to gradually distract the device, by advancing the teeth of the male component along the teeth of the female component, until cervical alignment and/or lordosis has been restored.
10. Loosen the set screw and distract the device to achieve compression between the implant and the adjacent vertebral end plates. Continue distracting until normal spine contour or lordosis is restored. Tighten the set screw to maintain the desired length of the **TPS** device.
11. Pack additional allograft cancellous bone into the device through the bone graft holes.
12. Adjust the variable drill guide to the appropriate screw length. Thread the drill guide into the screw guide and hand drill a 2mm pilot hole into the adjacent promontory. The drill guide prevents the drill from advancing past the desired hole depth. If the cortical promontory of the vertebra is nonexistent or of poor quality, thread the drill guide into one of the two optional screw holes in the bone flange and drill the 2mm pilot hole. These optional screw holes may also be used if limited exposure or anatomical interference makes the screw guides unattainable with the drill guide.

NOTE: Due to screw interference, it is **impossible** to use **both** the screw guide holes and the optional screw holes to secure the bone flange. It is **possible**, however, to use one screw guide hole and the opposite optional screw hole to secure the bone flange to the vertebrae.

13. Remove the drill guide and thread the temporary lag screw through the screw guide and into the adjacent vertebra. It is important that the flanges of the device are flush on the adjacent vertebrae during securing of the temporary lag screws.
14. Repeat Steps 12 and 13 for the remaining temporary lag screws. The temporary lag screws, a total of three, will assist in holding the implant flush to the adjacent vertebra during insertion of the bone screws. For the last screw hole, adjust the variable drill guide to the appropriate screw length, thread the drill guide into the screw guide and hand drill a 2mm pilot hole into the adjacent promontory.
15. Remove the drill guide and thread the bone screw through the screw guide and into the adjacent vertebra. Tighten the bone screw until the threads of the bone screw lock into the threads of the device. Again, it is important that the flanges of the device are flush on the adjacent vertebrae during securing of the bone screws. When the bone screw is secured, the top of the screw head will be flush with the screw guide. The self tapping fluted 4mm x 18mm bone screw is used with the screw guide holes. Through the optional screw holes it is possible to engage the anterior and posterior cortical bone of the adjacent vertebrae. A total of five bone screws of varying lengths are available to achieve bi-cortical purchase. These 4mm bone screws come in lengths of 14, 16, 18, 20 and 22mm. The bi-cortical screws have blunt tips to minimize injury to the spinal cord should the screws exit the posterior cortical bone. The bi-cortical screws are also secured into the device through the threaded locking mechanism.
16. Remove one lag screw at a time and thread the bone screw through the screw guide and into the adjacent vertebra. Tighten the bone screw until the threads of the bone screw lock into the threads of the device. Again, it is important that the flanges of the device are flush on the adjacent vertebrae during securing of the bone screws. When the bone screw is secured, the top of the screw head will be flush with the screw guide. Repeat this step for the two remaining screw holes.
17. With the distractor, apply a counter torque while tightening the set screw. Tighten until the head of the set screw shears off at approximately 4 N-m, locking the male and female components together.
18. Obtain an intraoperative lateral x-ray to confirm proper placement and to verify that cervical alignment and/or lordosis has been restored.
19. Recheck the tightness of all bone screws and verify that the top of the bone screws are flush with the screw guides.
20. Irrigate the wound, remove the retractors, inspect for hemostasis, and re-irrigate thoroughly.
21. Standard two layer wound closure, drain per surgeon preference.

NOTE: The **Biomet TPS Spinal System Surgical Technique Manual** should be carefully followed. It supplies important information on proper usage of the implants and instruments. For a more detailed description of the surgical technique and supporting photographs of the major steps, please refer to the **Biomet TPS Spinal System Surgical Technique Manual**.

CONTRAINDICATIONS

Contraindications include, but are not limited to,

1. anticipated survival of < three months,
2. skeletal immaturity, mental incompetence or confinement,
3. evidence of deep vein thrombosis,
4. localized or systemic infection,
5. severe osteoporosis,
6. rheumatoid arthritis,
7. acute renal failure,
8. known congestive heart failure or ejection fraction of <35% or unstable angina or considered by cardiology to be a high risk for surgery,
9. poor nutritional status, e.g., low serum albumin level or body weight <70% ideal for the patient's age, height and gender,
10. uncorrectable coagulopathy.

WARNINGS

The **Biomet TPS** Spinal System implant must only be implanted by a fully qualified surgeon. Even with the use of **TPS** Spinal System implants by a qualified surgeon, a successful result in terms of pain, function, or fusion is not always achieved.

Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together in building a construct. No components of the **Biomet TPS** Spinal System should be used with the components from any other system or manufacturer. As with all orthopaedic implants, the **Biomet TPS** Spinal System components should never be reused under any circumstances.

PRECAUTIONS

Preoperative:

The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments. All implants and instruments must be unpacked, inspected for damage, including scratches or notches, cleaned and sterilized prior to use in the operative field.

Intraoperative:

The **Biomet TPS** Spinal System is for single use only and must not be reused. The **Biomet TPS** Spinal System Surgical Technique Manual should be carefully followed. Extreme caution should be used around the spinal cord and nerve roots. Breakage, slippage, misuse or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.

Postoperative:

The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation. The patient should be instructed in the limitations of physical activities which would place excessive stresses on the implants or cause delay in the healing process. The patient should also be instructed in the proper use of external braces or any other assist device that may be required.

COMPLICATIONS

Possible adverse effects include, but are not limited to,

1. bending, loosening or fracture of the implants or instruments,
2. metal sensitivity to a foreign body, including possible tumor formation,
3. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications,
4. nonunion or delayed union,
5. infection,
6. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage,
7. urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium,
8. pain or discomfort,
9. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery,
10. hemorrhage of blood vessels and/or hematomas,
11. stroke,
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height,
13. bursitis,
14. inability to resume activities of normal daily living,
15. death.

STERILITY

The **Biomet TPS** Spinal System is provided nonsterile. All packaging should be sealed and intact upon receipt. If the package or product is damaged, it should not be used and should be returned immediately.

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycle is recommended:

Method:	Steam
Cycle:	Pre-vacuum
Temperature:	270°F (132°C)
Exposure Time:	8 minutes
Drying Time:	20 minutes

NOTE: It is recommended to dry and/or cool the parts to prevent condensation after the steam cycle.

CAUTION

NOT FOR SALE IN THE UNITED STATES.

INFORMATION

For further information, please contact the Customer Service Department at:

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