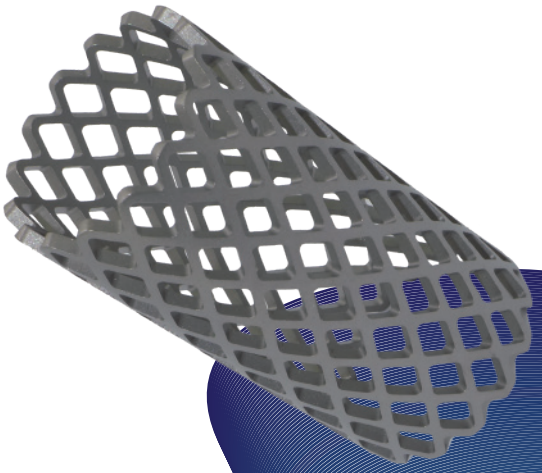
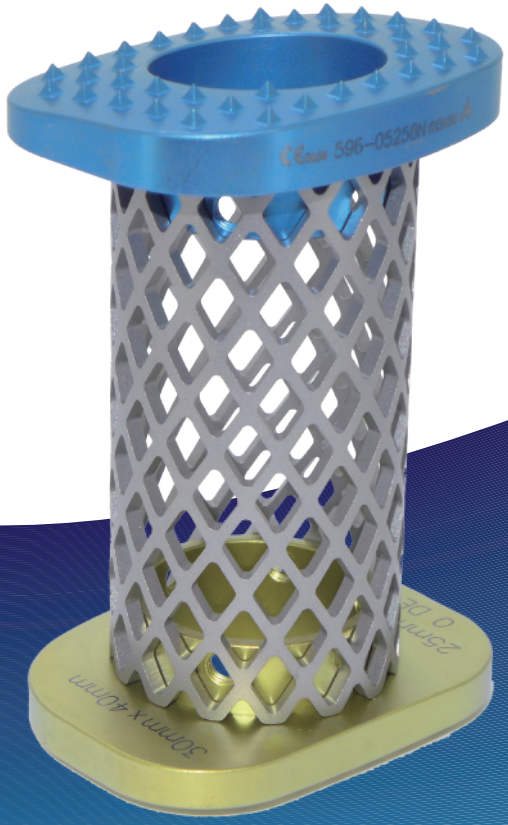
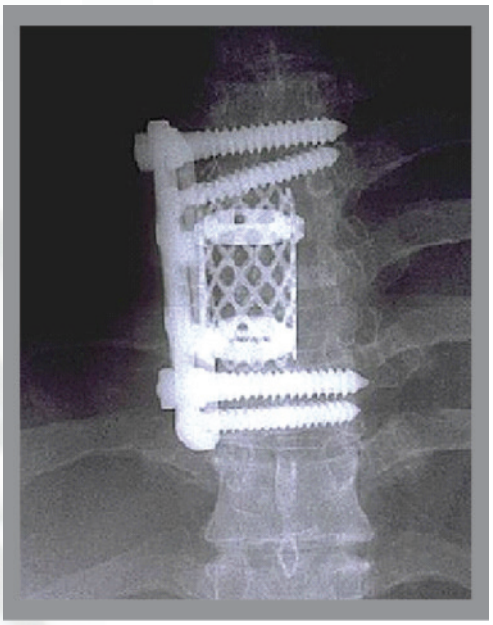
A-Mesh®

Spinal Titanium Mesh

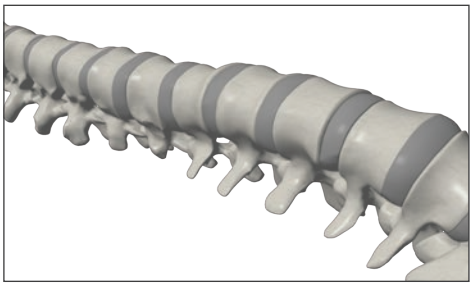


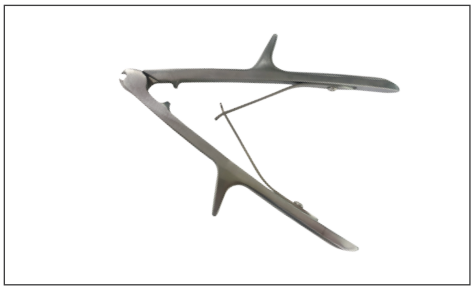


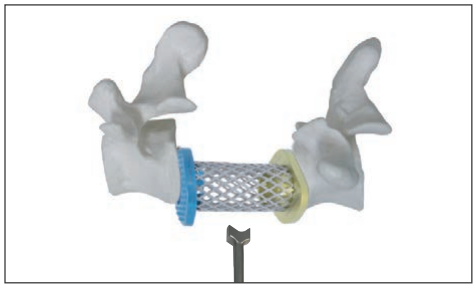


A-SPINE

Contents







Description

A-Mesh® Spinal Titanium Mesh is designed to restore biomechanical integrity throughout the thoracic and lumbar spine following vertebrectomy or corpectomy for patients with spine tumors or fractures. The system provides anterior, middle and posterior vertebral column support both immediately after surgery and for prolonged periods in the absence of bone fusion.

Indications

A-Mesh® Spinal Titanium Mesh is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. A-Mesh® Spinal Titanium Mesh is also indicated for use in vertebral fracture or unstable.

Contraindications

Contraindications include, but not limited to patients with:

1. Severe osteoporosis.
2. Vertebral fracture or disease with any active or suspected latent infection.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases.

Sterilization

The implants and instruments are delivered non sterile. Before use needed cleaned and sterilized recommended to be steam sterilized refer to "A-SPINE Reprocessing Manual" following process parameters:
Steam Wrapped Gravity Cycle at 121 °C/250 °F for 30 minutes.
If need more information, the "Intended for Use" and "A-SPINE Reprocessing Manual" can be downloaded from A-SPINE official website: http://www.aspine.com.tw/

Possible Adverse Effects and Warnings

Possible Adverse Effects

Patients should be advised prior to implantation surgery the possible side effects of such surgeries including:

1. Spinal surgery complications: genito-urinary system functional syndrome, gastro-intestinal system functional syndrome,cardiovascular circulatory functional syndrome (including thrombosis), bronchopulmonary syndrome (including pulmonary embolism), bursitis, hematorrhea, myocardial infarction , infection, paralysis or death.
2. Operation resulting in pachymeninx damage, neuropathogenesis, nerve damage, disease position ossification, vessel and nerve obstacle.
3. Pain, discomfort, or abnormal sensations due to the presence of the device.
4. Due to improper implantation, inflammation, early loading and trauma result in loosening, bending, fracture or dislocation.
5. Delayed or non union of the grafted mass and pseudoarthrosis.
6. Allergic reactions to implant material.
7. Decrease in bone density due to bone absorption or stress shielding.
8. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Possible side effects including but not limited to the above, may necessitate further surgical treatment.

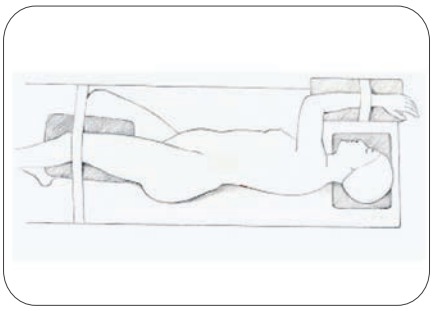
Warnings

1. Surgeons should be familiar with surgical procedures and techniques. Beware of surgical practice should be followed by avoiding contaminated wounds or infection.
2. Implant should be handled extremely in care.Inspect all components preoperatively to assure utility.
3. Appropriate and correct size selection of implant is very important.Using proper size of implant may decrease the risk of the surgery and increase the successful rate of surgery.
4. Implant is a single use product and reused implant is strictly prohibited. Even though the implant does not undamage, but may still have some risk to lead to small defects.
5. Patient should be well instructed about the implant. The implants have their limitations and patient should realize that implants are not as strong as healthy human bone. Post operative care is one of the main reason that may assure the success rate of surgery.
6. Improper activities may lead to implants displaced or damaged , migration of the implant may be occured.
   Therefore another surgical operation probably will take place to remove the implant.

Surgical Technique

Patient Position

The patient is positioned on the operating table in the lateral decubitus position with patient' s left side up. The transpleural approach for the thoracolumbar region and the standard retroperitoneal approach for the lower lumbar region is recommended .



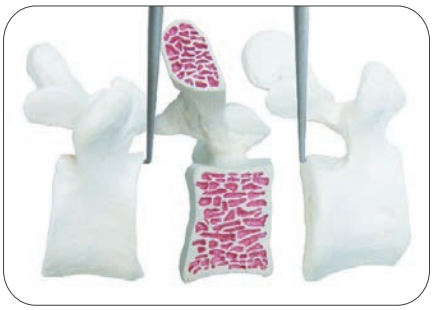
Vertebrectomy

Use C-arm to determine the correct approach. The involved segments of the vertebral column are exposed . If necessary, the resection of the vertebral body(bodies) including the adjacent disc(s) is performed.

Determine Implant Size

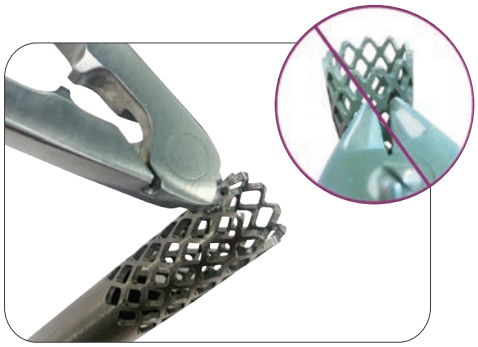
The Calipers (405-5201) can be used to determine the height of the defect.

Use the Trial Driver (405-0801) to attach the Trial (405-0601~405-0607), and measure the size of mesh plate.



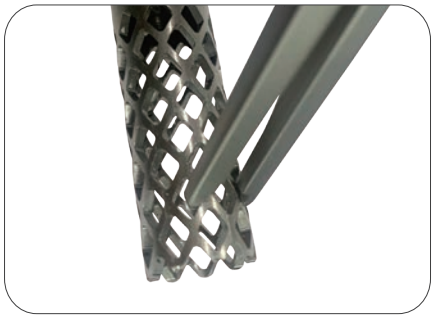
Cut

Trim the mesh to the appropriate height by using the Cutter (405-2701) which leans against the conjunct area to ensure the maximum contact.
Usually you can hear "click" when cut off the mesh.



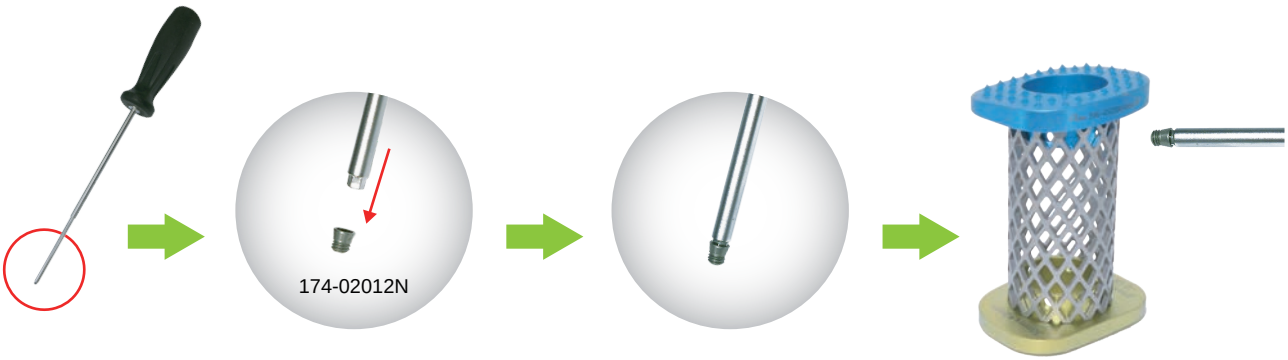
Caution:

Trimming the conjunct area or shake the cutter vigorously can damage the cutter and mesh.



Assemble the Mesh Plate and the Mesh

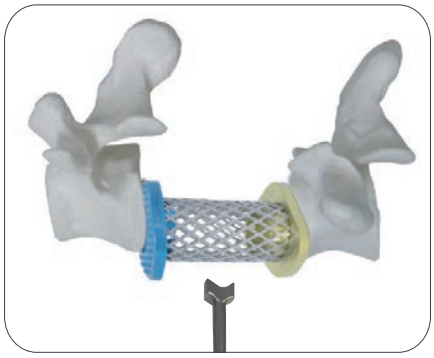
The 2.5mm Hex Screw Driver (202-3001) has screw self-holding mechanism.
Choose the appropriate degree size of the Mesh Plate to attach the Mesh and fixation by the Set Screws.



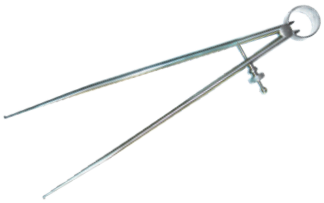
This screw driver (405-3302) with self holding screws mechanism.

Insertion

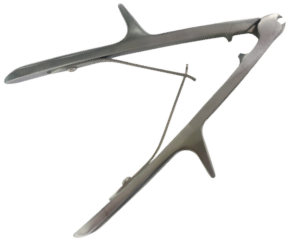
Use the Holder (405-1301) to hold the mesh to the defect and insert it by using the Impactor (405-3001).



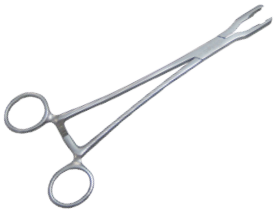
Instruments



405-5201
Caliper



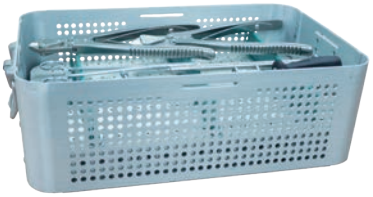
405-2701
Cutter



405-1301
Holder

405-3001
Impactor

405-0801
Trial driver



99901-031
Implants / Instruments Case

202-1302
Screw Holder
*for optional

Ø30 Ø25 Ø20 Ø16 Ø14 Ø12 Ø10

202-3301
2.5mm Hex screw driver
*for optional

405-0601 Ø10mm Trial
405-0602 Ø12mm Trial
405-0603 Ø14mm Trial
405-0604 Ø16mm Trial
405-0605 Ø20mm Trial
405-0606 Ø25mm Trial
405-0607 Ø30mm Trial
405-0608 Ø35mm Trial *for optional

◆ Instruments Cleaning

1. All implants and instruments should be cleaned by ultrasonic cleaner with distilled water for 5 minutes.
   Caution: The use of sodium hydroxide (NaOH) is prohibited.
2. Avoid the use of corrosive products and/or instruments including abrasive sponges and metal brushes.
3. Verify that all instruments are in operative condition prior to sterilization.

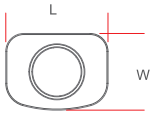
System Components

Mesh Spacer

Length	20 mm	50 mm	70 mm	90 mm
Ø 10mm	596-10202	596-10502	596-10702	
Ø 12mm	596-12202	596-12502	596-12702	
Ø 14mm	596-14202	596-14502	596-14702	
Ø 16mm	596-16202	596-16502	596-16702	
Ø 20mm	596-20202	596-20502	596-20702	596-20902
Ø 25mm	596-25202	596-25502	596-25702	596-25902
Ø 30mm	596-30202	596-30502	596-30702	596-30902

Mesh Plate

Angulation	0°	5°
Ø 10mm	596-00102	596-05102
Ø 12mm	596-00122	596-05122
Ø 14mm	596-00142	596-05142
Ø 16mm	596-00162	596-05162
Ø 20mm	596-00202	596-05202
Ø 25mm	596-00252	596-05252
Ø 30mm	596-00302	596-05302



Angulation		0°	5°
Ø 10mm	L29 x W19mm	596-00148N	596-05148N
Ø 12mm	L35 x W25mm	596-00208N	596-05208N
Ø 14mm	L40 x W30mm	596-00258N	596-05258N

Set Screw

Length	L 3.5mm
Ø 3mm	174-02012

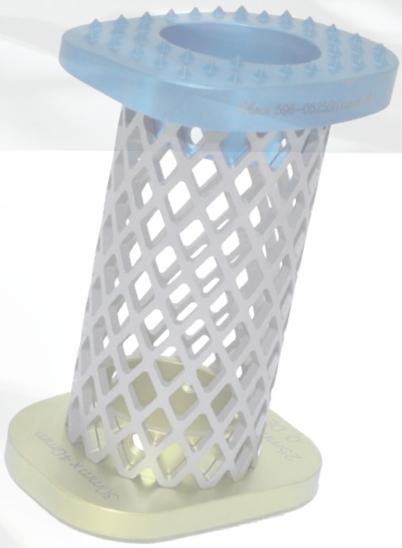
Length	L 3.5mm
Ø 3mm	174-02012N

NOTE

NOTE

NOTE

A-Mesh



A-SPINE

A-SPINE Asia Co.,Ltd.

20F., No.80, Section 1, Chenggong Road, Yonghe District,
New Taipei City 234634, Taiwan
Tel:+886-2-2926-7088 Fax:+886-2-2926-7396
E-mail:service@aspine.com.tw www.aspine.com.tw

T-VBR-001-CE/2022-11-15