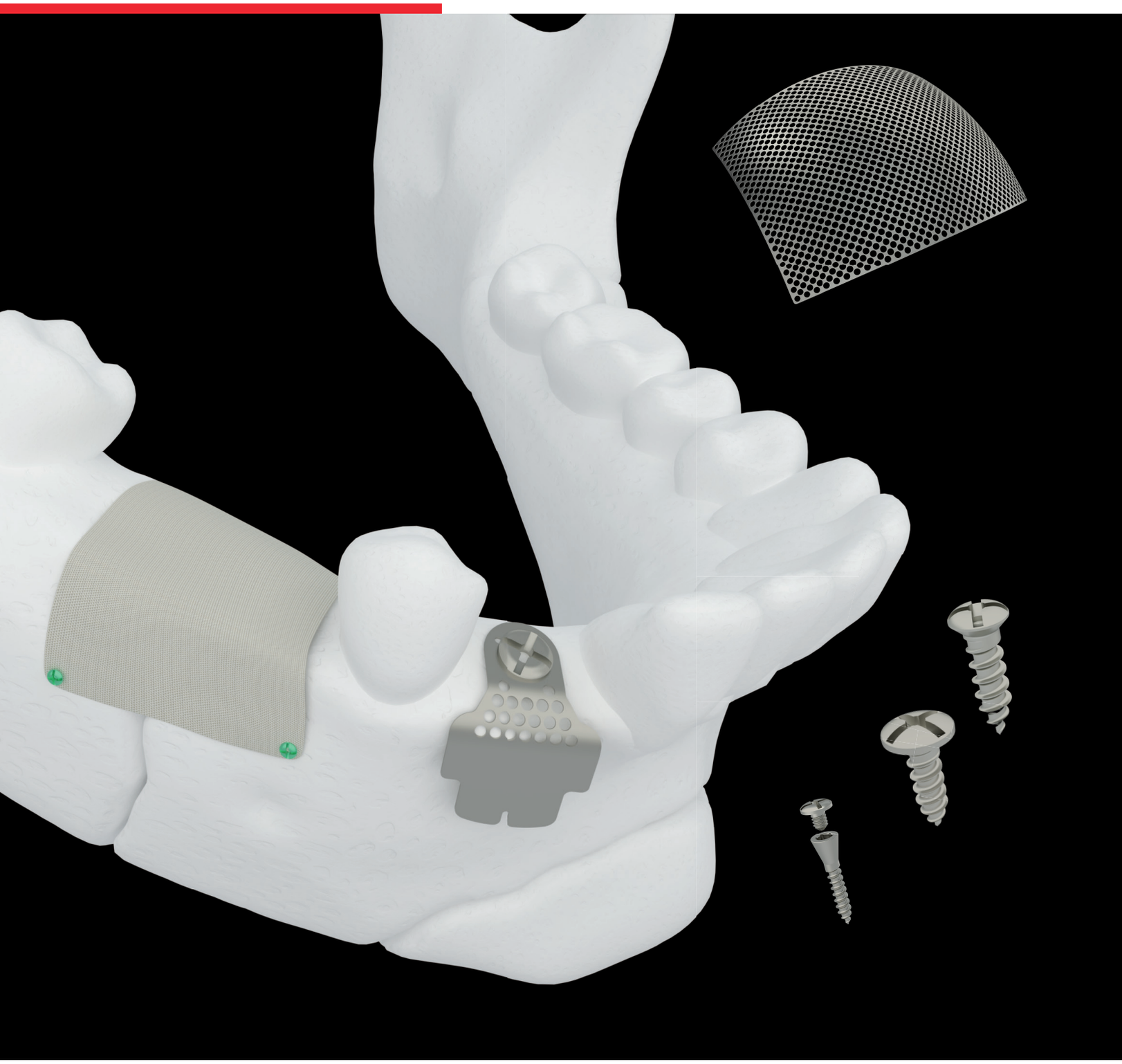
MEMBRANE
FIXATION SYSTEM



MEDICAL CONCEPT INNOVATION

Device Description

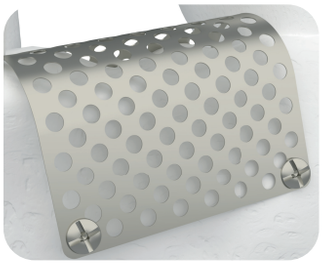
MCI – Membrane Fixation System is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.

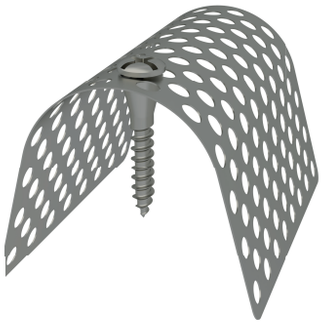
The MCI – Membrane Fixation System is a rigid fixation consisting of plates and screws in various configurations, shapes and sizes as follows:

The MCI – Membrane Fixation System is made of Unalloyed Titanium and Titanium Alloy (Ti-6AL-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known bio-compatibility.

The device screw is available in three different types, Self-Drilling Screw MFS, Self-Drilling Tenting Screw MFS and the Self-Drilling Screw MFS WH. The Self-Drilling Screw MFS is for stabilizing the mesh plate. The Self-Drilling Screw MFS WH has a wide head (WH) design which is well suited for the meshes. The Self-Drilling Tenting Screw MFS is comprised with a body and a cap. It is effective to maintain the space between the mesh and the bone.

- The Self-Drilling Screw MFS WH provided with head diameter 3.0 mm, thread diameter 1.5 mm, and length from 3.0 mm to 12.0 mm.
- The Self-Drilling Screw MFS, provided with head diameter 2.5 mm, thread diameter 1.5 mm, and length from 3.0 mm to 12.0 mm
- The Self-Drilling Tenting Screw MFS provided with head diameter 2.7 mm, thread diameter 1.5 mm and length 10.0 mm.



General Information

- The Meshes are very thin, soft and elastic but has a strong membrane with good suture retention. The extremely high flexibility of this mesh plate allows free fitting, even to irregular surfaces.
- The MFS Meshes are suited for horizontal and vertical bone volume augmentation of implants sites using guided bone. The MFS Meshes are suitable for multi-case situations; the product allows bone formation and spatial retention for stable implant. The MFS Meshes have flexibility with thin thickness, and the pre-cut design makes the desired shape form easier.
- The device system also includes various manual surgical instruments, such as mesh puncher, screw-driver handle, screw block, driver shaft and drill bit.

Self-Drilling Screw MFS 1.5 TI-Cross-Drive

Code	Length	Head Diameter	Outer Diameter
A01.01.0500	3mm	Ø 2.5mm	Ø 1.5mm
A01.01.0501	4mm		
A01.01.0502	5mm		
A01.01.0503	6mm		
A01.01.0504	8mm		
A01.01.0505	10mm		
A01.01.0506	12mm		

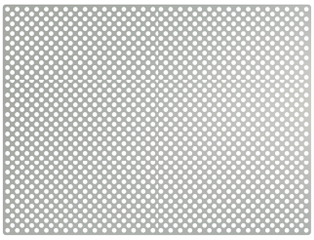
Self-Drilling Screw MFS WH TI-Cross-Drive

Code	Length	Head Diameter	Outer Diameter
A01.01.0507	3mm	Ø 3.0mm	Ø 1.5mm
A01.01.0508	4mm		
A01.01.0509	5mm		
A01.01.0510	6mm		
A01.01.0511	8mm		
A01.01.0512	10mm		
A01.01.0513	12mm		

Self-Drilling Tenting Screw MFS

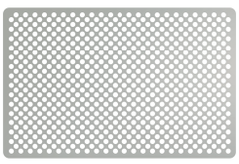
Code	Size	Head Diameter	Outer Diameter
A01.01.0514	10mm	Ø 2.7mm	Ø 1.5

Micro Mesh MFS



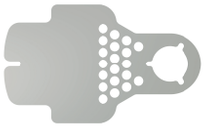
Code	Size	Tickness	Pore Diameter
A01.01.4500	37x24mm	0.1mm	Ø 1.58
A01.01.4501	37x24mm	0.2mm	Ø 1.88
A01.01.4502	49x37mm	0.1mm	Ø 1.58
A01.01.4503	49x37mm	0.2mm	Ø 1.88
A01.01.4504	99x74mm	0.1mm	Ø 1.58
A01.01.4505	99x74mm	0.2mm	Ø 1.88

Micro Mesh MFS Micro Pore



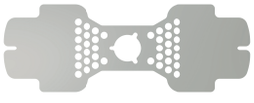
Code	Size	Tickness	Pore Diameter
A01.01.4506	37x25.1mm	0.1	Ø 0.8
A01.01.4507	37x25.1mm	0.2	Ø 0.8
A01.01.4508	37x24mm	0.1	Ø 0.8
A01.01.4509	37x24mm	0.2	Ø 0.8

Micro Mesh MFS Single Hole Mesh

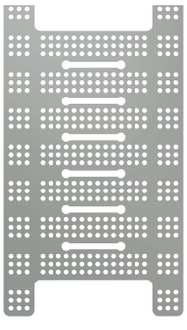


Code	Size	Tickness	Pore Diameter
A01.01.4510	16.6x10mm	0.15	Ø 0.8

Micro Mesh MFS Double Hole Mesh

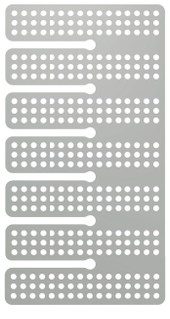


Code	Size	Tickness	Pore Diameter
A01.01.4511	28x10mm	0.15	Ø 0.8



Micro Mesh MFS Vertical

Code	Size	Tickness	Pore Diameter
A01.01.4512	53x29.9mm	0.15	Ø 0.8



Micro Mesh MFS Vertical

Code	Size	Tickness	Pore Diameter
A01.01.4513	41x21.9mm	0.15	Ø 0.8

Indications for Use

MCI – Membrane Fixation System is intended to stabilize and fixate bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.

Intended User Profile

MCI – Membrane Fixation System medical devices are intended to be used by qualified surgeons, with prior planning, in a sterile room (hospital). The devices need to be sterilized prior to use, and according the recommendations provided on the IFU. The devices are for single use.

Meshes

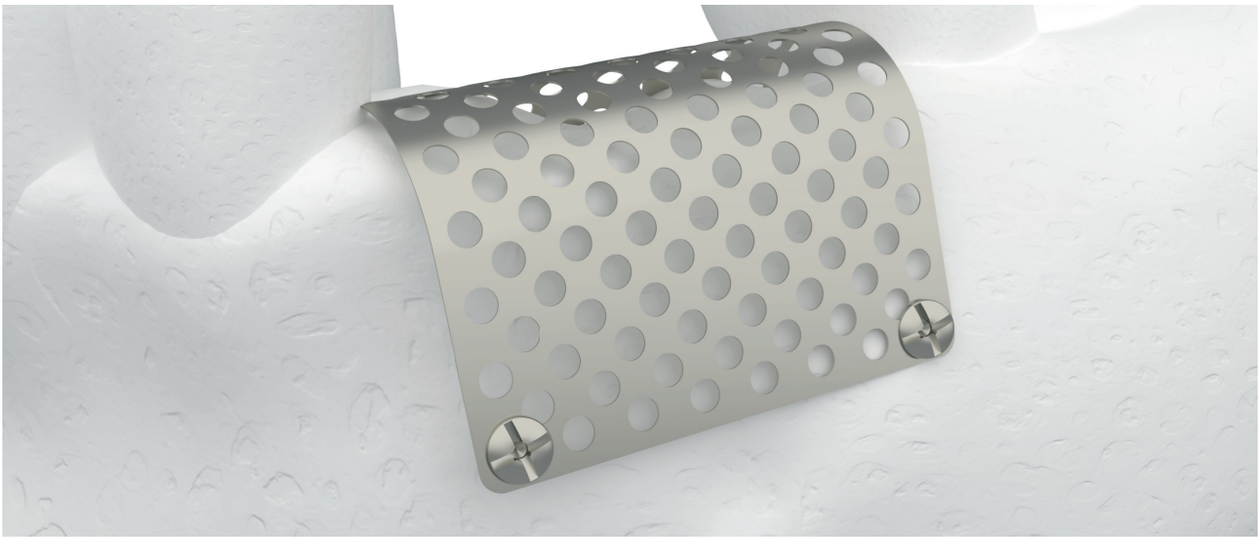
MCI – Membrane Fixation System (titanium mesh) is a non-absorbable titanium mesh made of pure Titanium (ASTM F67) that helps bone neoformation, acting as a biological barrier preventing the migration of epithelial cells, from the connective tissue and/or bacteria that would cause bone growth inhibition. They have a variety of lengths, widths, thicknesses and holes diameters.

The titanium mesh provides excellent biocompatibility, occlusive property, has permeability allowing nutrient transit, ease of use, as it is very malleable and can be cropped for site adaptations surgical procedures, has the ability to maintain an intact regenerative space and the possibility of vascularization of the graft by the two sides (periosteum and endosseum). It is designed to ensure three-dimensional reconstruction of alveolar bone defects and facilitate bone replacement through proper replacement material fixation.

The perforations in the mesh allow for the diffusion of interstitial fluid, but do not allow cell invasion connective and epithelial tissue. Because it has memory, it can be pre-molded to the defect and fixed with screws to grafting and fixation to the bone surface (does not come with the product).

The titanium mesh conforms to the fabric's contours and still has enough rigidity to maintain space over the bone defect and the covering tissue. It is important to use Micro Mesh MFS (titanium mesh) temporarily so that it promotes a suitable environment, allowing the body to use its natural healing potential and regenerate lost or missing tissue.

The stay required to start osteoconduction is at least 21 days.



Medical device to be used in conjunction with this product

MCI also provides to the surgeons the instruments for a correct applicataion of the bone meshes and proper placement of the screws at surgery site. The instruments are sold unitarily.

The below table shows the complete list of class 1 exempt instruments to be used in conjunction with the MCI – Membrane Fixation System. The table contain description, compatible system, raw material, specific intended use and registration number.

The devices need to be sterilized prior to use, and according the recommendations provided on the IFU. The devices are for single use.

Instruments used in conjunction with MCI - CMF System

Article	Description	Raw Material	Specific Indication	Registration
A02.01.2200	Quick-coupling Handle for Screw-drive	STAINLESS STEEL AISI 304	Allow transbucal access.	D442866
A02.01.2201	Screwdriver Manipulation Tip for Membrane		Keep away the cheeks during the surgical pro-cedure.	D442866
A02.01.2202	Contra-Angle Screwdriver Tip for Membrane	TITANIUM GRADE 5	Assist the manipulation of other parts such as wrenches, drills, rods and trocar.	D442866
A02.01.2203	Contra-Angle Screwdriver Tip	STAINLESS STEEL AISI 304	Assist in directing drill at the time of bone drilling.	D442866
A02.01.2204	Membrane Positioner		Assist in directing the tip when inserting the screw.	D442866
A02.01.2205	Blue PPSU Box CMF P1	STAINLESS STEEL AISI 420	Modules plates so that they fit the shape of the bone anatomy.	D442868
A02.01.2206	Membrane Screw Case			D442868

A02.01.2200 Quick-coupling Handle for Screwdrive

A02.01.2201 Screwdriver Manipulation Tip for Membrane

A02.01.2202 Contra-Angle Screwdriver Tip for Membrane

A02.01.2203 Contra-Angle Screwdriver Tip

A02.01.0600 Screwdriver Manipulation Tip 1.5

A02.01.2204 Membrane Positioner

Rev. 01|2022
Illustrative images only

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CERTIFICATIONS

ISO13485
MDSAP - Medical Devices Single Audit Program