

FICHA TÉCNICA DE PRODUCTO MAIO REGEN

Marca Comercial:

MaioRegen

Diferentes configuraciones:

MaioRegen Prime

MaioRegen Slim

MaioRegen Chondro+

Fabricante:

Fin-ceramica Faenza S.p.A.

Dirección:

Vía Granarolo, 177/3- 48018 Faenza (RA) - Italy

Referencias:

Ver Anexo I

Clasificación:

Tipo III

Descripción:

Implante multicapa tridimensional de colágeno que mimetiza la matriz extracelular del cartílago y hueso subcondral

Indicación:

Tratamiento de lesiones focales de cartílago sintomáticas grado III (Condrales) y IV (Osteocondrales) de la escala de I.C.R.S.

Método acción:

La composición química particular permite que la línea de dispositivos MaioRegen imite la matriz extracelular del cartílago y el tejido osteocartilago. Los dispositivos de alta porosidad y buena hidrofiliicidad favorecen la rápida absorción de los líquidos biológicos (y componentes celulares relacionados) con los que entran en contacto durante la implantación, facilitando su adaptación al sitio de la lesión. La composición y la macro, micro y nanoestructura de los dispositivos favorecen los procesos de reparación de la superficie articular y permiten la reabsorción fisiológica mediada por células de los biomateriales implantados junto con el proceso de remodelación del tejido recién formado.

Imagen de producto:

Material/ Composición: Implante multicapa tridimensional de colágeno de origen animal tipo I (capa superficie articular 100% colágeno tipo I) y Magnesio-Hidroxiapatita altamente porosa (capa contacto hueso suncondral 30% colágeno tipo I + 70% Mg-HA Porosa)

Indicaciones: .Tratamiento de lesiones focales de cartilago sintomáticas grado III (Condrales) y IV (Osteocondrales) según Outerbridge

Destinado a Pacientes:

- edades comprendidas entre 15 y 60 años;
- con un índice de masa corporal (IMC) ≤30;
- que muestran lesiones condrales u osteocondrales de las superficies articulares: o de origen traumático, postraumático o degenerativo, o resultante de osteocondritis disecante; o con afectación del tejido subcondral ausente, leve, moderada o grave; o único o múltiple;
- o con un área total de lesión inferior a 10 cm2 en una sola articulación.

MaioRegen Prime: tratamiento de lesiones osteocondrales con afectación severa del hueso subcondral, como:

- lesiones traumáticas, postraumáticas y degenerativas de grado IVa y IVb según la clasificación ICRS;
- lesiones de grado IV según la clasificación de Outerbridge;
- lesiones en etapa temprana de osteoartritis (OA temprana según la definición de Luyten, Knee Surg Sports Traumatol Arthrosc., 2012) y lesiones de grado I y II según la clasificación de Kellgren y Lawrence, en ausencia de osteofitos;
- Lesiones resultantes de la osteocondritis disecante

MaioRegen Slim: .Tratamiento de lesiones osteocondrales con afectación moderada del hueso subcondral, como:

- lesiones traumáticas, postraumáticas y degenerativas de grado IVa según la clasificación ICRS;
- lesiones de grado IV según la clasificación de Outerbridge;
- lesiones en etapa temprana de osteoartritis (OA temprana según la definición de Luyten, Knee Surg Sports Traumatol Arthrosc., 2012) y lesiones de grado I y II según la clasificación de Kellgren y Lawrence, en ausencia de osteofitos.

MaioRegen Chondro+: .Tratamiento de lesiones del cartilago con alteración leve o nula del hueso subcondral, como:

- Lesiones traumáticas y postraumáticas de grado III según la clasificación ICRS y de grado III-IV según la clasificación de Outerbridge.

Contra indicaciones: No utilice el dispositivo en caso de:

- alergia establecida al colágeno equino y a las sales de fosfato cálcico;
- edad menor de 15 años y mayor de 60 años;
- obesidad (Índice de masa corporal: IMC > 30);
- lesiones condrales u osteocondrales con un área total superior a 10 cm2 por articulación tratada;
- lesiones en espejo;
- osteoartritis avanzada;
- infección sistémica o localizada;
- enfermedades inflamatorias sistémicas (por ejemplo, artritis reumatoide) o locales (por ejemplo, sinovitis);
- hipercalcemia;
- enfermedad ósea degenerativa sistémica o vascular (por ejemplo, osteonecrosis);
- trastornos de la coagulación o condiciones que impiden la curación;
- trastornos metabólicos que pueden afectar la reparación del tejido esquelético;
- trastornos del sistema inmunológico que pueden comprometer la reparación del tejido esquelético;
- tratamiento de quimioterapia y/o radioterapia en curso.

Envasado: Sistema de barrera estéril además de embalaje protector por fuera, esterilizado mediante rayos gamma

Medidas caja: 15 x 11 x 3,7 cm

Peso: 92gr / caja

Conservación y Almacenamiento: Almacenamiento en condiciones estándar de higiene sanitaria. Proteger de la contaminación. Mantener en temperatura entre 10°C y 30°C

Garantía de calidad: CE 0373 // ISO 9001:2015 // ISO 13485:2016

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ANEXO I: Referencias de Producto MaioRegen

Listado Modelos de Producto:			
MAIOREGEN			
REFERENCIA	DESCRIPCIÓN	UDI	FABRICANTE
01600286	MaioRegen Prime 3,0 x 4,0 x 0,6 cm	18054188160970	Fin-ceramica Faenza S.p.A.
01600288	MaioRegen Prime 2,0 x 3,0 x 0,6 cm	18054188161007	Fin-ceramica Faenza S.p.A.
01600275	MaioRegen Prime Ø = 1,5 cm H = 0,6 cm	18054188161236	Fin-ceramica Faenza S.p.A.
01600285	MaioRegen Prime Ø = 1,2 cm H = 0,6 cm	18054188160963	Fin-ceramica Faenza S.p.A.
01600291	MaioRegen Prime Ø = 1,8 cm H = 0,6 cm	18054188161069	Fin-ceramica Faenza S.p.A.
01600287	MaioRegen Slim 3,0 x 4,0 x 0,4 cm	18054188160987	Fin-ceramica Faenza S.p.A.
01600289	MaioRegen Slim 2,0 x 3,0 x 0,4 cm	18054188161014	Fin-ceramica Faenza S.p.A.
01600290	MaioRegen Slim Ø = 1,5 cm H = 0,4 cm	18054188161311	Fin-ceramica Faenza S.p.A.
01600282	MaioRegen Slim Ø = 1,2 cm H = 0,4 cm	18054188161045	Fin-ceramica Faenza S.p.A.
01600292	MaioRegen Slim Ø = 1,8 cm H = 0,4 cm	18054188161076	Fin-ceramica Faenza S.p.A.
01600400	MaioRegen Chondro+ 3,0 x 4,0 x 0,2 cm	18054188160994	Fin-ceramica Faenza S.p.A.
01600401	MaioRegen Chondro+ 2,0 x 3,0 x 0,2 cm	18054188161021	Fin-ceramica Faenza S.p.A.
01600403	MaioRegen Chondro+ Ø = 1,2 cm H = 0,2 cm	18054188161052	Fin-ceramica Faenza S.p.A.
01600404	MaioRegen Chondro+ Ø = 1,8 cm H = 0,2 cm	18054188161083	Fin-ceramica Faenza S.p.A.
01600405	MaioRegen Chondro+ Ø = 1,5 cm H = 0,2 cm	18054188161090	Fin-ceramica Faenza S.p.A.