MR Safety Information

MR Conditional

The Graft Markers are MR conditional to 3-Tesla or less. Visit the Genesee BioMedical website for more information.
www.geneseebiomedical.com/clinician-resources

Sterilization

THE PRODUCT MUST BE STERILIZED BEFORE USE.

Remove the product from the plastic bag prior to sterilization and wrap or place in a suitable container for sterilization. Use the hospital standard procedure for steam autoclaving. The responsibility for the sterility of the product rests entirely with the user. Following the initial opening of the plastic bag containing the bulk distal markers, the responsibility for the cleanliness of the product rests entirely with the user.

References

(1) Halseth WL, Elliott DP, Walker EL, Meza F: Angiographic restudy of coronary artery bypass grafts simplified by a marker. Clin. Cardiol. 1, 169-172 (1978)

Manufacturing Facility:
Genesee BioMedical, Inc.
700 W. Mississippi Ave. Unit D5
Denver, CO 80223-4509, USA

Toll-Free: (800) 786-4890
Phone: (303) 777-3000
Fax: (303) 777-8866
www.geneseebiomedical.com

Part No. 295023R05

Genesee BIOMEDICAL, INC.
Design beyond standard

ANASTOMARK• BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS

For marking the distal and jump anastomoses of saphenous vein grafts to the coronary arteries and the anastomoses of the internal mammary arteries to the coronary arteries.

Storage and Handling Instructions

Store at room temperature, in a dry place, out of direct sunlight.

Description

The Genesee BioMedical Anastomark® Distal Coronary Artery Bypass Graft Markers are implantable, surgical stainless-steel, radiopaque markers. They serve as radiographic indicators to allow the cardiologist to visualize the sites of the distal anastomoses so that graft and anastomotic patency and the location of coronary artery stenoses may be determined (1) prior to any future coronary angioplasty or reoperation. The distal marker is a smooth 316L stainless-steel 3.5 mm diameter ring (2 mm internal diameter).

Indications for Use

The Anastomark® distal coronary artery bypass graft markers are indicated for use in patients undergoing coronary artery bypass graft surgery or vascular graft surgery.

How Supplied

The Genesee BioMedical ANASTOMARK® bulk distal markers are supplied clean, **NON-STERILE**, retained on a stainless-steel clip, 20 per clip, packaged in a plastic bag. Bulk distal markers are available in quantities as follows: 100, 500, 1000, and 2000 per order.

MR Safety Information

MR Conditional

The Graft Markers are MR conditional to 3-Tesla or less. Visit the Genesee BioMedical website for more information.
www.geneseebiomedical.com/clinician-resources

Sterilization

THE PRODUCT MUST BE STERILIZED BEFORE USE.

Remove the product from the plastic bag prior to sterilization and wrap or place in a suitable container for sterilization. Use the hospital standard procedure for steam autoclaving. The responsibility for the sterility of the product rests entirely with the user. Following the initial opening of the plastic bag containing the bulk distal markers, the responsibility for the cleanliness of the product rests entirely with the user.

References

(1) Halseth WL, Elliott DP, Walker EL, Meza F: Angiographic restudy of coronary artery bypass grafts simplified by a marker. Clin. Cardiol. 1, 169-172 (1978)

Manufacturing Facility:
Genesee BioMedical, Inc.
700 W. Mississippi Ave. Unit D5
Denver, CO 80223-4509, USA

Toll-Free: (800) 786-4890
Phone: (303) 777-3000
Fax: (303) 777-8866
www.geneseebiomedical.com

Part No. 295023R05

Genesee BIOMEDICAL, INC.
Design beyond standard

ANASTOMARK• BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS

For marking the distal and jump anastomoses of saphenous vein grafts to the coronary arteries and the anastomoses of the internal mammary arteries to the coronary arteries.

Storage and Handling Instructions

Store at room temperature, in a dry place, out of direct sunlight.

Description

The Genesee BioMedical Anastomark® Distal Coronary Artery Bypass Graft Markers are implantable, surgical stainless-steel, radiopaque markers. They serve as radiographic indicators to allow the cardiologist to visualize the sites of the distal anastomoses so that graft and anastomotic patency and the location of coronary artery stenoses may be determined (1) prior to any future coronary angioplasty or reoperation. The distal marker is a smooth 316L stainless-steel 3.5 mm diameter ring (2 mm internal diameter).

Indications for Use

The Anastomark® distal coronary artery bypass graft markers are indicated for use in patients undergoing coronary artery bypass graft surgery or vascular graft surgery.

How Supplied

The Genesee BioMedical ANASTOMARK® bulk distal markers are supplied clean, **NON-STERILE**, retained on a stainless-steel clip, 20 per clip, packaged in a plastic bag. Bulk distal markers are available in quantities as follows: 100, 500, 1000, and 2000 per order.

Caution
Federal law (USA) restricts this product to sale by or on the order of a physician.

Product Code
Genesee BioMedical ANASTOMARK® Bulk Distal Markers - AMGM-BD

Contraindications
There are no known contraindications for use (except patients with known sensitivity to nickel or chromium, where their use may be contraindicated).

Instructions for Use
Immediately following the anastomosis of the saphenous vein, jump, or internal mammary artery graft to coronary artery anastomosis, the marker may be tied to the anastomotic suture. Alternatively, a separate 6.0 (or larger) non-absorbable suture may be used to attach the marker ring to the epicardium, immediately adjacent to the anastomotic site.

Precautions
Take care not to damage the marker rings during handling. Discard each stainless-steel retaining clip when the last marker has been removed.

Warnings
<u>THE PRODUCT MUST BE STERILIZED BEFORE USE.</u> Do not restrict or occlude the graft at the anastomotic site when attaching the marker. The stainless-steel clip is <u>NOT</u> implantable, surgical-grade stainless steel.

Disclaimer of Warranty
ALTHOUGH THE GENESEE BIOMEDICAL BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS, HEREINAFTER REFERRED TO AS “PRODUCT”, HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, GENESEE BIOMEDICAL HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS HANDLED AND USED. GENESEE BIOMEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GENESEE BIOMEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON, EXCEPT THE CHIEF EXECUTIVE OFFICER OR PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusion and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of the Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Caution
Federal law (USA) restricts this product to sale by or on the order of a physician.

Product Code
Genesee BioMedical ANASTOMARK® Bulk Distal Markers - AMGM-BD

Contraindications
There are no known contraindications for use (except patients with known sensitivity to nickel or chromium, where their use may be contraindicated).

Instructions for Use
Immediately following the anastomosis of the saphenous vein, jump, or internal mammary artery graft to coronary artery anastomosis, the marker may be tied to the anastomotic suture. Alternatively, a separate 6.0 (or larger) non-absorbable suture may be used to attach the marker ring to the epicardium, immediately adjacent to the anastomotic site.

Precautions
Take care not to damage the marker rings during handling. Discard each stainless-steel retaining clip when the last marker has been removed.

Warnings
<u>THE PRODUCT MUST BE STERILIZED BEFORE USE.</u> Do not restrict or occlude the graft at the anastomotic site when attaching the marker. The stainless-steel clip is <u>NOT</u> implantable, surgical-grade stainless steel.

Disclaimer of Warranty
ALTHOUGH THE GENESEE BIOMEDICAL BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS, HEREINAFTER REFERRED TO AS “PRODUCT”, HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, GENESEE BIOMEDICAL HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS HANDLED AND USED. GENESEE BIOMEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GENESEE BIOMEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON, EXCEPT THE CHIEF EXECUTIVE OFFICER OR PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusion and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of the Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Caution
Federal law (USA) restricts this product to sale by or on the order of a physician.

Product Code
Genesee BioMedical ANASTOMARK® Bulk Distal Markers - AMGM-BD

Contraindications
There are no known contraindications for use (except patients with known sensitivity to nickel or chromium, where their use may be contraindicated).

Instructions for Use
Immediately following the anastomosis of the saphenous vein, jump, or internal mammary artery graft to coronary artery anastomosis, the marker may be tied to the anastomotic suture. Alternatively, a separate 6.0 (or larger) non-absorbable suture may be used to attach the marker ring to the epicardium, immediately adjacent to the anastomotic site.

Precautions
Take care not to damage the marker rings during handling. Discard each stainless-steel retaining clip when the last marker has been removed.

Warnings
<u>THE PRODUCT MUST BE STERILIZED BEFORE USE.</u> Do not restrict or occlude the graft at the anastomotic site when attaching the marker. The stainless-steel clip is <u>NOT</u> implantable, surgical-grade stainless steel.

Disclaimer of Warranty
ALTHOUGH THE GENESEE BIOMEDICAL BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS, HEREINAFTER REFERRED TO AS “PRODUCT”, HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, GENESEE BIOMEDICAL HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS HANDLED AND USED. GENESEE BIOMEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GENESEE BIOMEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON, EXCEPT THE CHIEF EXECUTIVE OFFICER OR PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusion and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of the Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Caution
Federal law (USA) restricts this product to sale by or on the order of a physician.

Product Code
Genesee BioMedical ANASTOMARK® Bulk Distal Markers - AMGM-BD

Contraindications
There are no known contraindications for use (except patients with known sensitivity to nickel or chromium, where their use may be contraindicated).

Instructions for Use
Immediately following the anastomosis of the saphenous vein, jump, or internal mammary artery graft to coronary artery anastomosis, the marker may be tied to the anastomotic suture. Alternatively, a separate 6.0 (or larger) non-absorbable suture may be used to attach the marker ring to the epicardium, immediately adjacent to the anastomotic site.

Precautions
Take care not to damage the marker rings during handling. Discard each stainless-steel retaining clip when the last marker has been removed.

Warnings
<u>THE PRODUCT MUST BE STERILIZED BEFORE USE.</u> Do not restrict or occlude the graft at the anastomotic site when attaching the marker. The stainless-steel clip is <u>NOT</u> implantable, surgical-grade stainless steel.

Disclaimer of Warranty
ALTHOUGH THE GENESEE BIOMEDICAL BULK DISTAL CORONARY ARTERY BYPASS GRAFT MARKERS, HEREINAFTER REFERRED TO AS “PRODUCT”, HAVE BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, GENESEE BIOMEDICAL HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS HANDLED AND USED. GENESEE BIOMEDICAL, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. GENESEE BIOMEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON, EXCEPT THE CHIEF EXECUTIVE OFFICER OR PRESIDENT OF GENESEE BIOMEDICAL, HAS ANY AUTHORITY TO BIND GENESEE BIOMEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusion and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of the Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.